RULES
OF
THE TENNESSEE DEPARTMENT OF HEALTH
BOARD FOR LICENSING HEALTH CARE FACILITIES

CHAPTER 1200-08-29
STANDARDS FOR HOME CARE ORGANIZATIONS
PROVIDING HOME MEDICAL EQUIPMENT

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1200-08-29-.01 DEFINITIONS.

(1) Administrator. A person who:

(a) Is a licensed physician with at least one (1) year of supervisory or administrative experience in home health care, hospice care or related health programs; or

(b) Is a registered nurse with at least one (1) year of supervisory or administrative experience in home health care, hospice care or related health programs; or

(c) Has training and experience in health service administration and at least one (1) year of supervisory or administrative experience in home health care, hospice care or related health programs.

(2) Advance Directive. A written statement such as a living will, a durable power of attorney for health care or a do not resuscitate order relating to the provision of health care when the individual is incapacitated.

(3) Agency. A Home Care Organization providing home medical equipment.

(4) Assistive Technology Practitioner (ATP). Service providers primarily involved in evaluating the consumer's needs and training in the use of a prescribed wheeled mobility device.

(5) Assistive Technology Supplier (ATS). Service providers involved in the sale and service of commercially available wheeled mobility devices.

(6) Board. The Tennessee Board for Licensing Health Care Facilities.

(7) Cardiopulmonary Resuscitation (CPR). The administering of any means or device to support cardiopulmonary functions in a patient, whether by mechanical devices, chest compressions, mouth-to-mouth resuscitation, cardiac massage, tracheal intubation, manual or mechanical ventilations or respirations, defibrillation, the administration of drugs and/or chemical agents intended to restore cardiac and/or respiratory functions in a patient where cardiac or respiratory arrest has occurred or is believed to be imminent.

(8) Clinical Note. A written and dated notation containing a patient assessment, responses to medications, treatments, services, any changes in condition and signed by a health team member who made contact with the patient.

(Rule 1200-08-29-.01, continued)

(9) Commissioner. The Commissioner of the Tennessee Department of Health or his or her authorized representative.

(10) Competent. For the purpose of this chapter only, a patient who has decision-making capacity.

~~(11) Corrective Action Plan/Report. A report filed with the department by the facility after reporting an unusual event. The report must consist of the following:~~

~~(a) the action(s) implemented to prevent the reoccurrence of the unusual event,~~

~~(b) the time frames for the action(s) to be implemented,~~

~~(c) the person(s) designated to implement and monitor the action(s), and~~

~~(d) the strategies for the measurements of effectiveness to be established.~~

(~~12~~11) Decision-making capacity. Decision-making capacity is shown by the fact that the person is able to understand the proposed procedure, its risks and benefits, and the available alternative procedures.

(~~13~~12) Department. The Tennessee Department of Health.

(~~14~~13) Do Not Resuscitate (DNR) Order. An order entered by the patient's treating physician in the patient's medical record which states that in the event the patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The order may contain limiting language to allow only certain types of cardiopulmonary resuscitation to the exclusion of other types of cardiopulmonary resuscitation.

(~~15~~14) Evaluation. The determination and documentation of the physiological and functional factors that impact the selection of an appropriate seating and wheeled mobility device.

(~~16~~15) Hazardous Waste. Materials whose handling, use, storage and disposal are governed by local, state or federal regulations.

(~~17~~16) Health care decision. A decision made by an individual or the individual's health care decision-maker, regarding the individual's health care including but not limited to:

(a) the selection and discharge of health-care providers and institutions;

(b) approval or disapproval of diagnostic tests, surgical procedures, programs of administration of medication, and orders not to resuscitate;

(c) directions to provide, withhold or withdraw artificial nutrition and hydration and all other forms of health care; and

(d) transfer to other health care facilities.

(~~18~~17) Health Care Decision-maker. In the case of an incompetent patient, or a patient who lacks decision-making capacity, the patient's health care decision-maker is one of the following: the patient's health care agent as specified in an advance directive, the patient's court-appointed legal guardian or conservator with health care decision-making authority, or the patient's surrogate as determined pursuant to Rule 1200-08-29-.13 or T.C.A. §33-3-220.

(Rule 1200-08-29-.01, continued)

(~~19~~18) Home Care Organization. As defined by T.C.A. § 68-11-201, a "home care organization" provides home health services, home medical equipment services or hospice services to patients on an outpatient basis in either their regular or temporary place of residence.

(~~20~~19) Home Medical Equipment.

(a) Medical equipment intended for use by the consumer including, but not limited to the following:

1. A device, instrument, apparatus, machine, or other similar article whose label bears the statement: "Caution: Federal law requires dispensing by or on the order of a physician.";
2. Ambulating assistance equipment;
3. Mobility equipment;
4. Rehabilitation seating;
5. Oxygen care equipment and oxygen delivery systems;
6. Respiratory care equipment and respiratory disease management devices.
7. Rehabilitation environmental control equipment;
8. Ventilators;
9. Apnea monitors;
10. Diagnostic equipment;
11. Feeding pumps;
12. A bed prescribed by a physician to treat or alleviate a medical condition;
13. Transcutaneous electrical nerve stimulator;
14. Sequential compression devices; and
15. Neonatal home phototherapy devices.

(b) Home medical equipment does not include:

1. Medical equipment used or dispensed in the normal course of treating patients by hospitals and nursing facilities as defied in this part, other than medical equipment delivered or dispensed by a separate unit or subsidiary corporation of a hospital or nursing facility or agency that is in the business of delivering home medical equipment to an individual's residence;
2. Upper and lower extremity prosthetics and related orthotics;
3. Canes, crutches, walkers, and bathtub grab bars;

(Rule 1200-08-29-.01, continued)

4. Medical equipment provided through a physician's office incident to a physician's service;

5. Equipment provided by a pharmacist which is used to administer drugs or medicine that can be dispensed only by a pharmacist; or

6. Enteral and parenteral equipment provided by a pharmacist.

(~~21~~20) Home medical equipment provider. Any person who provides home medical equipment services.

(~~22~~21) Home medical equipment services. A service provided by any person who sells or rents home medical equipment for delivery to the consumer' place of residence in this state, regardless of the location of the home medical equipment provider.

(~~23~~22) Incompetent. A patient who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.

(~~24~~23) Infectious Waste. Solid or liquid wastes which contain pathogens with sufficient virulence and quantity such that exposure to the waste by a susceptible host could result in an infectious disease.

(~~25~~24) Lacks Decision-Making Capacity. Lacks Decision-Making Capacity means the factual demonstration by the attending physician and the medical director, or the attending physician and another physician that an individual is unable to understand:

(a) A proposed health care procedure(s), treatment(s), intervention(s), or interaction(s);

(b) The risks and benefits of such procedure(s), treatment(s), intervention(s) or interaction(s); and

(c) The risks and benefits of any available alternative(s) to the proposed procedure(s), treatment(s), intervention(s) or interaction(s).

(~~26~~25) Legal Conservator. Any person authorized to act for the patient pursuant to any provision of T.C.A. Title 34, Chapters 5 and 11 through 13.

(~~27~~26) Legal Guardian. Any person authorized to act for the resident pursuant to any provision of T.C.A. §§34-5-102(4) or 34-11-101, or any successor statute thereto.

(~~28~~27) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.

(~~29~~28) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(~~30~~29) Life Threatening Or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

(~~31~~30) Medical Record. Information that pertains to confinement or services rendered to patients, including one or more of the following:

(a) medical histories;

(b) records;

(Rule 1200-08-29-.01, continued)

(c) reports;

(d) clinical notes;

(e) summaries; or

(f) orders.

If the patient does not require any clinical services from the home medical equipment company, the medical record will consist of the physician order only.

(~~32~~31) Medical Futile Treatment. Resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the patient or to achieve the expressed goals of the informed patient. In the case of the incompetent patient, the surrogate expresses the goals of the patient.

(~~33~~32) Patient. Includes but is not limited to any person who is suffering from an acute or chronic illness or injury or who is crippled, convalescent or infirm, or who is in need of obstetrical, surgical, medical, nursing or supervisory care.

(~~34~~33) Patient Abuse. Patient neglect, intentional infliction of pain, injury, or mental anguish. Patient abuse includes the deprivation of services by a caretaker which are necessary to maintain the health and welfare of a patient or resident; however, the withholding of authorization for or provision of medical care to any terminally ill person who has executed an irrevocable living will in accordance with the Tennessee Right to Natural Death Law, or other applicable state law, if the provision of such medical care would conflict with the terms of such living will shall not be deemed "patient abuse" for purposes of these rules.

(~~35~~34) Physician. A person currently licensed as such by the Tennessee Board of Medical Examiners or currently licensed by the Tennessee Board of Osteopathic Examination. For the purpose of this chapter only, a physician who is licensed to practice medicine or osteopathy in a state contiguous to Tennessee, who have previously provided treatment to the patient and has an ongoing physician-patient relationship with the patient for whom a referral is to be made, may refer a patient residing in this state to a home care organization providing hospice services duly licensed under this chapter. This shall not be construed as authorizing an unlicensed physician to practice medicine in violation of T.C.A. §§ 63-6-201 or 63-9-104.

(~~36~~35) Qualified Rehabilitation Professional. A health care professional with in the professional's scope of practice licensed under Title 63; or an individual who has appropriately obtained the designation of ATS or ATP, meeting all requirements thereof, as established by the Rehabilitation Engineering and Assistive Technology Society of North America (RESNA).

(~~37~~36) Registered Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(~~38~~37) Shall or Must. Compliance is mandatory.

(~~39~~38) Supervision. Authoritative procedural guidance by a qualified person for the accomplishment of a function or activity with initial direction and periodic inspection of the actual act of accomplishing the function or activity. Periodic supervision must be provided if the person is not a licensed or certified assistant, unless otherwise provided in accordance with these rules.

(Rule 1200-08-29-.01, continued)

(~~40~~39) Surrogate. The patient's conservator, or if none, a competent adult most likely to know the wishes of the patient with respect to the possible withholding of resuscitative services or withdrawal of resuscitative services.

~~(41) Unusual Event. The abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient that is not related to a natural course of the patient's illness or underlying condition.~~

~~(42) Unusual Event Report. A report form designated by the department to be used for reporting an unusual event.~~

(~~43~~40) Wheeled Mobility Device. A wheelchair or wheelchair and seated positioning system prescribed by a physician and required for use by the patient for a period of six (6) months or more. The following Medicare wheelchairs base codes are exempt: K0001, K0002, K0003, K0004, K0006, and K0007 as long as the consumer weighs less than three hundred (300) pounds.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-226, and 68-11-303.* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendment filed May 27, 2004; effective August 10, 2004. Amendment filed June 25, 2007; effective September 8, 2007. Amendment filed October 11, 2007; effective December 25, 2007. Amendments filed December 23, 2009; effective March 23, 2010.*

1200-08-29-.02 LICENSING PROCEDURES.

(1) No person, partnership, association, corporation or any state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate or maintain in the State of Tennessee any Home Care Organization providing home medical equipment without having a license. A license shall be issued to the person or persons named and only for the premises listed in the application for licensure. The name of the agency shall not be changed without first notifying the Department in writing. Licenses are not transferable or assignable and shall expire annually on June 30th. The license shall be conspicuously posted in the agency.

(2) In order to make application for a license:

(a) The applicant shall submit an application on a form prepared by the Department.

(b) Each applicant for a license shall pay an annual license fee in the amount of one thousand eighty dollars ($1,080.00). The fee must be submitted with the application and is not refundable.

(c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the Department. Patients shall not be admitted to the agency until a license has been issued. Applicants shall not hold themselves out to the public as being an agency until the license has been issued. A license shall not be issued until the agency is in substantial compliance with these rules.

(d) The applicant must prove the ability to meet the financial needs of the agency.

(Rule 1200-08-29-.10, continued)

(5) Waste must be stored in a manner which preserves the integrity of the packaging, inhibits rapid microbial growth and putrefaction, and minimizes the potential of exposure or access by unknowing persons. Waste must be stored in a manner and location which affords protection from animals, precipitation, wind and direct sunlight, does not present a safety hazard, does not provide a breeding place or food source for insects or rodents, and does not create a nuisance.

(6) In the event of spills, ruptured packaging, or other incidents where there is a loss of containment of waste, the agency must ensure that proper actions are immediately taken to:

(a) Isolate the area;

(b) Repackage all spilled waste and contaminated debris in accordance with the requirements of this rule; and

(c) Sanitize all contaminated equipment and surfaces appropriately.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, and 68-11-209.* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000.*

1200-08-29-.11 RECORDS AND REPORTS.

~~(1) Unusual events shall be reported by the facility to the Department of Health in a format designed by the Department within seven (7) business days of the date of the identification of the abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient.~~

~~(a) The following represent circumstances that could result in an unusual event that is an unexpected occurrence or accident resulting in death, life threatening or serious injury to a patient, not related to a natural course of the patient's illness or underlying condition. The circumstances that could result in an unusual event include, but are not limited to:~~

~~1. medication errors;~~

~~2. aspiration in a non-intubated patient related to conscious/moderate sedation;~~

~~3. intravascular catheter related events including necrosis or infection requiring repair or intravascular catheter related pneumothorax;~~

~~4. volume overload leading to pulmonary edema;~~

~~5. blood transfusion reactions, use of wrong type of blood and/or delivery of blood to the wrong patient;~~

~~6. perioperative/periprocedural related complication(s) that occur within 48 hours of the operation or the procedure, including a procedure which results in any new central neurological deficit or any new peripheral neurological deficit with motor weakness;~~

~~7. burns of a second or third degree;~~

(Rule 1200-08-29-.11, continued)

8. falls resulting in radiologically proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage, and/or internal trauma, but does not include fractures resulting from pathological conditions;

9. procedure related incidents, regardless of setting and within thirty (30) days of the procedure and includes readmissions, which include:

(i) procedure related injury requiring repair or removal of an organ;

(ii) hemorrhage;

(iii) displacement, migration or breakage of an implant, device, graft or drain;

(iv) post operative wound infection following clean or clean/contaminated case;

(v) any unexpected operation or reoperation related to the primary procedure;

(vi) hysterectomy in a pregnant woman;

(vii) ruptured uterus;

(viii) circumcision;

(ix) incorrect procedure or incorrect treatment that is invasive;

(x) wrong patient/wrong site surgical procedure;

(xi) unintentionally retained foreign body;

(xii) loss of limb or organ, or impairment of limb if the impairment is present at discharge or for at least two (2) weeks after occurrence;

(xiii) criminal acts;

(xiv) suicide or attempted suicide;

(xv) elopement from the facility;

(xvi) infant abduction, or infant discharged to the wrong family;

(xvii) adult abduction;

(xviii) rape;

(xix) patient altercation;

(xx) patient abuse, patient neglect, or misappropriation of resident/patient funds;

(xxi) restraint related incidents; or

(xxii) poisoning occurring within the facility.

(b) Specific incidents that might result in a disruption of the delivery of health care services at the facility shall also be reported to the department, on the unusual event form,

(Rule 1200-08-29-.11, continued)

~~within seven (7) days after the facility learns of the incident. These specific incidents include the following:~~

~~1. strike by the staff at the facility;~~

~~2. external disaster impacting the facility;~~

~~3. disruption of any service vital to the continued safe operation of the facility or to the health and safety of its patients and personnel; and~~

~~4. fires at the facility which disrupt the provision of patient care services or cause harm to patients or staff, or which are reported by the facility to any entity, including but not limited to a fire department, charged with preventing fires.~~

~~(c) For health services provided in a "home" setting, only those unusual events actually witnessed or known by the person delivering health care services are required to be reported.~~

~~(d) Within forty (40) days of the identification of the event, the facility shall file with the department a corrective action report for the unusual event reported to the department. The department's approval of a Corrective Action Report will take into consideration whether the facility utilized an analysis in identifying the most basic or causal factor(s) that underlie variation in performance leading to the unusual event by (a) determining the proximate cause of the unusual event, (b) analyzing the systems and processes involved in the unusual event, (c) identifying possible common causes, (d) identifying potential improvements, and (e) identifying measures of effectiveness. The corrective action report shall either: (1) explain why a corrective action report is not necessary; or (2) detail the actions taken to correct any error identified that contributed to the unusual event or incident, the date the corrections were implemented, how the facility will prevent the error from recurring in the future and who will monitor the implementation of the corrective action plan.~~

~~(e) The department shall approve in writing, the corrective action report if the department is satisfied that the corrective action plan appropriately addresses errors that contributed to the unusual event and takes the necessary steps to prevent the recurrence of the errors. If the department fails to approve the corrective action report, then the department shall provide the facility with a list of actions that the department believes are necessary to address the errors. The facility shall be offered an informal meeting with the Commissioner or the Commissioner's representative to attempt to resolve any disagreement over the corrective action report. If the department and the facility fail to agree on an appropriate corrective action plan, then the final determination on the adequacy of the corrective action report shall be made by the Board after a contested case hearing.~~

~~(f) The event report reviewed or obtained by the department shall be confidential and not subject to discovery, subpoena or legal compulsion for release to any person or entity, nor shall the report be admissible in any civil or administrative proceeding other than a disciplinary proceeding by the department or the appropriate regulatory board. The report is not discoverable or admissible in any civil or administrative action except that information in any such report may be transmitted to an appropriate regulatory agency having jurisdiction for disciplinary or license sanctions against the impacted facility. The department must reveal upon request its awareness that a specific event or incident has been reported.~~

(Rule 1200-08-29-.11, continued)

~~(g) The department shall have access to facility records as allowed in Title 68, Chapter 11, Part 3. The department may copy any portion of a facility medical record relating to the reported event unless otherwise prohibited by rule or statute. This section does not change or affect the privilege and confidentiality provided by T.C.A. §63-6-219.~~

~~(h) The department, in developing the unusual event report form, shall establish an event occurrence code that categorizes events or specific incidents by the examples set forth above in (a) and (b). If an event or specific incident fails to come within these examples, it shall be classified as "other" with the facility explaining the facts related to the event or incident.~~

~~(i) This does not preclude the department from using information obtained under these rules in a disciplinary action commenced against a facility, or from taking a disciplinary action against a facility. Nor does this preclude the department from sharing such information with any appropriate governmental agency charged by federal or state law with regulatory oversight of the facility. However, all such information must at all times be maintained as confidential and not available to the public. Failure to report an unusual event, submit a corrective action report, or comply with a plan of correction as required herein may be grounds for disciplinary action pursuant to T.C.A. §68-11-207.~~

~~(j) The affected patient and/or the patient's family, as may be appropriate, shall also be notified of the event or incident by the facility.~~

~~(k) During the second quarter of each year, the Department shall provide the Board an aggregate report summarizing by type the number of unusual events and incidents reported by facilities to the Department for the preceding calendar year.~~

~~(l) The Department shall work with representatives of facilities subject to these rules, and other interested parties, to develop recommendations to improve the collection and assimilation of specific aggregate health care data that, if known, would track health care trends over time and identify system-wide problems for broader quality improvement. The goal of such recommendations should be to better coordinate the collection of such data, to analyze the data, to identify potential problems and to work with facilities to develop best practices to remedy identified problems. The Department shall prepare and issue a report regarding such recommendations.~~

(1) The home care organization providing home medical equipment shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

(2) The home care organization providing home medical equipment shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the home care organization providing home medical equipment or to the health and safety of its patients and personnel; and

(d) Fires at the home care organization providing home medical equipment that disrupt the provision of patient care services or cause harm to the patients or staff, or that are reported by the facility to any entity, including but not limited to a fire department charged with preventing fires.

(Rule 1200-08-29-.11, continued)

(23) Patient Records shall be maintained for each patient who receives in-home services. The patient record must contain detailed, accurate documentation that reflects all of the services or care provided, directly or by contract. The patient record shall contain at a minimum the following:

(a) Documentation of patient education and instruction;

(b) Physician orders as required;

1. A home care organization providing home medical equipment is authorized to receive and appropriately act on a written order for a plan of care for a patient concerning a home health service signed by a physician that is transmitted to the agency by electronically signed electronic mail. Such order that is transmitted by electronic mail shall be deemed to meet any requirement for written documentation imposed by this regulation.

(c) Documentation that patient has been fully informed of patient rights and responsibilities and at a minimum, the right to:

1. Be fully informed in advance about care and treatment to be provided by the agency;

2. Be fully informed in advance of any changes in the care or treatment to be provided by the agency when those changes may affect the patient's well-being;

3. Voice grievances without fear of discrimination or reprisal;

4. Confidentiality of personal information;

5. Have one's property treated with respect; and

6. Be fully informed of the agency's telephone number for information, questions, and/or complaints about services provided by the agency and a description of the process for investigating and resolving complaints. The agency shall investigate and resolve all patient complaints and document the results in a timely manner. The agency shall label all equipment with the name, address, and telephone number of the agency.

(34) Patient Confidentiality. The agency shall have written policies dealing with patient information. Patient records shall contain signed release of information statements/forms when the agency bills a third-party payor or shares information with others outside the agency. Patient confidentiality polices will address, at a minimum, the following:

(a) A definition of confidential information;

(b) Persons/positions authorized to release confidential information;

(c) Conditions which warrant release of confidential information;

(d) Persons to whom confidential information may be released;

(e) Policies and procedures for obtaining signatures on, using, and filing release of information forms;

(Rule 1200-08-29-.11, continued)

(f) Who has authority to review patient records; and

(g) A statement that training in confidentiality is mandatory for all employees, so that personnel are knowledgeable about and consistently follow confidentiality polices and procedures.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-209, and 68-11-260.* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed September 1, 2004; effective November 15, 2004. Amendment filed February 23, 2007; effective May 9, 2007.*

1200-08-29-.12 PATIENT RIGHTS.

(1) Each patient has at least the following rights:

(a) To privacy in treatment and personal care;

(b) To be free from mental and physical abuse. Should this right be violated, the agency must notify the Department within five (5) business days and the Tennessee Department of Human Services, Adult Protective Services immediately;

(c) To refuse treatment. The patient must be informed of the consequences of that decision, and the refusal and its reason must be reported to the treating physician and documented in the medical record;

(d) To refuse experimental treatment and drugs. The patient's written consent for participation in research must be obtained and retained in his or her medical record; and

(e) To have his or her records kept confidential and private. Written consent by the patient must be obtained prior to release of information except to persons authorized by law. If the patient is mentally incompetent, written consent is required from the patient's legal representative. The agency must have policies to govern access and duplication of the patient's record.

(2) Each patient has a right to self-determination, which encompasses the right to make choices regarding life-sustaining treatment, including resuscitative services. This right of self-determination may be effectuated by an advance directive.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, and 68-11-209.* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000.*

1200-08-29-.13 REPEALED.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-224.* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000. Amendment filed April 28, 2003; effective July 12, 2003. Repeal filed September 1, 2004; effective November 15, 2004.*

1200-08-29-.14 DISASTER PREPAREDNESS.

(1) All agencies shall establish and maintain communications with the local office of the Tennessee Emergency Management Agency. This includes the provision of the information

RULES
OF
DEPARTMENT OF HEALTH
BOARD FOR LICENSING HEALTH CARE FACILITIES

CHAPTER 1200-08-32
STANDARDS FOR END STAGE RENAL DIALYSIS CLINICS

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1200-08-32-.01 DEFINITIONS.

(1) Adult. An individual who has capacity and is at least 18 years of age.

(2) Advance Directive. An individual instruction or a written statement relating to the subsequent provision of health care for the individual, including, but not limited to, a living will or a durable power of attorney for health care.

(3) Agent. An individual designated in an advance directive for health care to make a health care decision for the individual granting the power.

(4) Anticoagulant. A medication or medical technique to prevent or slow down coagulation and clotting.

(5) Anticoagulation. The process of inhibiting the blood clotting mechanism by the administration of certain drugs.

(6) Artificial Kidney. An apparatus which removes metabolic wastes or other poisons from the body when the natural kidneys are not functioning properly. This apparatus may be referred to as a kidney dialyzer.

(7) Board. The Tennessee Board for Licensing Health Care Facilities.

(8) Capacity. An individual's ability to understand the significant benefits, risks, and alternatives to proposed health care and to make and communicate a health care decision. These regulations do not affect the right of a patient to make health care decisions while having the capacity to do so. A patient shall be presumed to have capacity to make a health care decision, to give or revoke an advance directive, and to designate or disqualify a surrogate. Any person who challenges the capacity of a patient shall have the burden of proving lack of capacity.

(9) Cardiopulmonary Resuscitation (CPR). The administering of any means or device to restore or support cardiopulmonary functions in a patient, whether by mechanical devices, chest compressions, mouth-to-mouth resuscitation, cardiac massage, tracheal intubation, manual or mechanical ventilations or respirations, defibrillation, the administration of drugs and/or chemical agents intended to restore cardiac and/or respiratory functions in a patient where cardiac or respiratory arrest has occurred or is believed to be imminent.

(Rule 1200-08-32-.01, continued)

(10) Chronic Hemodialysis. Hemodialysis over a long period of time, usually to the extent of the patient's life or organ transplant.

(11) Commissioner. The Commissioner of the Tennessee Department of Health or his or her authorized representative.

(12) Competent. A patient who has capacity.

~~(13) Corrective Action Plan/Report. A report filed with the department by the facility after reporting an unusual event. The report must consist of the following:~~

~~(a) the action(s) implemented to prevent the reoccurrence of the unusual event,~~

~~(b) the time frames for the action(s) to be implemented,~~

~~(c) the person(s) designated to implement and monitor the action(s), and~~

~~(d) the strategies for the measurements of effectiveness to be established.~~

(~~14~~13) Department. The Tennessee Department of Health.

(~~15~~14) Designated Physician. A physician designated by an individual or the individual's agent, guardian, or surrogate, to have primary responsibility for the individual's health care or, in the absence of a designation or if the designated physician is not reasonably available, a physician who undertakes such responsibility.

(~~16~~15) Dialysis. A process by which substances are removed from a patient's body by diffusion and convection from one fluid compartment to another across a semipermeable membrane. The two types of dialysis that are currently in common use are hemodialysis and peritoneal dialysis.

(~~17~~16) Dialysis technician. An individual who is not a registered nurse or physician and who provides dialysis care under the direct supervision of a registered nurse or physician. If unlicensed, this individual may also be known as a patient care technician, dialysis assistant or dialysis technician.

(~~18~~17) Dietitian. A person currently licensed as such by the Tennessee Board of Dietitian/Nutritionist Examiners or exempted from licensure by T.C.A. §63-25-104 and having at least one (1) year of experience in clinical nutrition.

(~~19~~18) Do Not Resuscitate (DNR) Order. An order entered by the patient's treating physician in the patient's medical record which states that in the event the patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The order may contain limiting language to allow only certain types of cardiopulmonary resuscitation to the exclusion of other types of cardiopulmonary resuscitation.

(~~20~~19) Emancipated Minor. Any minor who is or has been married or has by court order or otherwise been freed from the care, custody and control of the minor's parents.

(~~21~~20) Emergency Responder. A paid or volunteer firefighter, law enforcement officer, or other public safety official or volunteer acting within the scope of his or her proper function under law or rendering emergency care at the scene of an emergency.

(~~22~~21) End-Stage Renal Disease (ESRD). That stage of renal impairment that is or appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.

(Rule 1200-08-32-.01, continued)

(~~23~~22) Guardian. A judicially appointed guardian or conservator having authority to make a health care decision for an individual.

(~~24~~23) Hazardous Waste. Materials whose handling, use, storage, and disposal are governed by local, state or federal regulations.

(~~25~~24) Health Care. Any care, treatment, service or procedure to maintain, diagnose, treat, or otherwise affect an individual's physical or mental condition, and includes medical care as defined in T.C.A. § 32-11-103(5).

(~~26~~25) Health Care Decision. Consent, refusal of consent or withdrawal of consent to health care.

(~~27~~26) Health Care Decision-maker. In the case of a patient who lacks capacity, the patient's health care decision-maker is one of the following: the patient's health care agent as specified in an advance directive, the patient's court-appointed guardian or conservator with health care decision-making authority, the patient's surrogate as determined pursuant to Rule 1200-08-32-.13 or T.C.A. §33-3-220, the designated physician pursuant to these Rules or in the case of a minor child, the person having custody or legal guardianship.

(~~28~~27) Health Care Institution. A health care institution as defined in T.C.A. § 68-11-1602.

(~~29~~28) Health Care Provider. A person who is licensed, certified or otherwise authorized or permitted by the laws of this state to administer health care in the ordinary course of business or practice of a profession.

(~~30~~29) Home dialysis. Dialysis performed by a trained patient on him or herself or by a trained designated caregiver on the patient at the patient's home with little or no professional assistance.

(~~31~~30) Home dialysis training. A training program that teaches dialysis patients and patient caregivers to perform home dialysis.

(~~32~~31) Hospital. Any institution, place, building or agency represented and held out to the general public as ready, willing and able to furnish care, accommodations, facilities and equipment for the use, in connection with the services of a physician or dentist, of one (1) or more nonrelated persons who may be suffering from deformity, injury or disease or from any other condition for which nursing, medical or surgical services would be appropriate for care, diagnosis or treatment.

(~~33~~32) Hospitalization. The reception and care of any person for a continuous period longer than twenty-four (24) hours, for the purpose of giving advice, diagnosis, nursing service or treatment bearing on the physical health of such person, and maternity care involving labor and delivery for any period of time.

(~~34~~33) Incompetent. A patient who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.

(~~35~~34) Individual instruction. An individual's direction concerning a health care decision for the individual.

(~~36~~35) Infectious Waste. Solid or liquid wastes which contain pathogens with sufficient virulence and quantity such that exposure to the waste by a susceptible host could result in an infectious disease.

(Rule 1200-08-32-.01, continued)

(~~37~~36) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(~~38~~37) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.

(~~39~~38) Life Threatening or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

(~~40~~39) Medical Director. A physician who: (1) Is board eligible or board certified in nephrology, internal medicine or pediatrics by a professional board, and has at least 12 months of experience or training in the care of patients at ESRD facilities; or (2) During the 5-year period prior to September 1, 1976, served for at least 12 months as director of a dialysis or transplantation program; and worked within the field of kidney dialysis for at least 12 months in the past 5 years. However, in the areas where a physician who meets the definition in paragraph (1) or (2) of this definition is not available to direct a dialysis facility, another physician may direct the facility, subject to the approval of the Department.

(~~41~~40) Medical Emergency. A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the patient's health in serious jeopardy, serious impairment to bodily functions or serious dysfunction of any bodily organ or part.

(~~42~~41) Medical Record. Medical histories, records, reports, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries, x-rays, radiology interpretations and other written, electronic, or graphic data prepared, kept, made or maintained in a facility that pertains to confinement or services rendered to patients.

(~~43~~42) Medically Inappropriate Treatment. Resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the patient or other medical or surgical treatments to achieve the expressed goals of the informed patient. In the case of the incompetent patient, the patient's representative expresses the goals of the patient.

(~~44~~43) NFPA. The National Fire Protection Association.

(~~45~~44) Nurse Manager. A Registered Nurse who is employed full time in a renal dialysis clinic, is currently licensed as such by the Tennessee Board of Nursing, and (1) has at least 12 months of experience in clinical nursing, and an additional 6 months of experience in nursing care of the patient with permanent kidney failure or undergoing kidney transplantation, including training in and experience with the dialysis process; or (2) Has at least 18 months of experience in nursing care of the patient on maintenance dialysis, or in nursing care of the patient with a kidney transplant, including training in and experience with the dialysis process. If the Nurse Manager is in charge of self-care dialysis training, at least 3 months of the total required ESRD experience must be in training patients in self-care.

(~~46~~45) Nurse Practitioner/Clinical Nurse Specialist. A person currently licensed as a registered nurse by the Tennessee Board of Nursing and certified by the American Academy of Nurse Practitioners, the American Nurses Credentialing Center as a nurse practitioner or holds a certification as clinical nurse specialist from the Tennessee Board of Nursing.

(~~47~~46) Nursing Personnel. Licensed nurses and certified nurse aides, who provide nursing care.

(~~48~~47) On-Duty/On-Site. A staff person who is on the facility's premises and has the obligation to carry out any job responsibilities designated in his/her job description.

(Rule 1200-08-32-.01, continued)

(~~49~~48) On-Site. A staff person who is on the facility's premises but is only required to be on duty during an emergency.

(~~50~~49) Patient Abuse. Patient neglect, intentional infliction of pain, injury, or mental anguish. Patient abuse includes the deprivation of services by a caretaker which are necessary to maintain the health and welfare of a patient; however, the withholding of authorization for or provision of medical care to any terminally ill person who has executed an irrevocable living will in accordance with the Tennessee Right to Natural Death Law, or other applicable state law, if the provision of such medical care would conflict with the terms of such living will shall not be deemed "patient abuse" for purposes of these rules.

(~~51~~50) Patient Care Plan. A written document prepared by the interdisciplinary team for a patient receiving end stage renal disease services.

(~~52~~51) Person. An individual, corporation, estate, trust, partnership, association, joint venture, government, governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.

(~~53~~52) Personally Informing. A communication by any effective means from the patient directly to a health care provider.

(~~54~~53) Physician. An individual authorized to practice medicine or osteopathy under Tennessee Code Annotated, Title 63, Chapters 6 or 9.

(~~55~~54) Physician's Assistant. A person who is currently licensed by the Tennessee Board of Medical Examiners and Committee on Physician Assistants and has obtained prescription writing authority pursuant to T.C.A. 63-19-107(2)(A).

(~~56~~55) Power of Attorney for Health Care. The designation of an agent to make health care decisions for the individual granting the power under T.C.A. Title 34, Chapter 6, Part 2.

(~~57~~56) Qualified Emergency Medical Service Personnel. Includes, but shall not be limited to, emergency medical technicians, paramedics, or other emergency services personnel, providers, or entities acting within the usual course of their professions, and other emergency responders.

(~~58~~57) Reasonably Available. Readily able to be contacted without undue effort and willing and able to act in a timely manner considering the urgency of the patient's health care needs. Such availability shall include, but not be limited to, availability by telephone.

(~~59~~58) Referring physician. The physician who refers the patient to the renal dialysis clinic for treatment.

(~~60~~59) Renal dialysis clinic. Any institution, facility, place or building devoted to the provision of renal dialysis on an outpatient basis to persons diagnosed with end stage renal disease.

(~~61~~60) Registered Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(~~62~~61) Shall or Must. Compliance is mandatory.

(~~63~~62) Social Worker. A person who is licensed by the Tennessee Board of Social Worker Certification and Licensure, if applicable, and (1) Has completed a course of study with specialization in clinical practice at, and holds a masters degree from, a graduate school of social work accredited by the Council on Social Work Education; or (2) Has served for at least

(Rule 1200-08-32-.01, continued)

2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program and has established a consultative relationship with a social worker who qualifies in paragraph (1) of this definition.

(~~64~~63) State. A state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.

(~~65~~64) Supervising Health Care Provider. The designated physician or, if there is no designated physician or the designated physician is not reasonably available, the health care provider who has undertaken primary responsibility for an individual's health care.

(~~66~~65) Surrogate. An individual, other than a patient's agent or guardian, authorized to make a health care decision for the patient.

(~~67~~66) Survey. An on-site examination by the Department to determine compliance with state and federal regulations.

(~~68~~67) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the patient.

(~~69~~68) Treating Physician. The physician selected by or assigned to the patient and who has the primary responsibility for the treatment and care of the patient. Where more than one physician shares such responsibility, any such physician may be deemed to be the "treating physician."

(69) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

~~(70) Universal Do Not Resuscitate Order. A written order that applies regardless of the treatment setting and that is signed by the patient's physician which states that in the event the patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The Physician Order for Scope of Treatment (POST) form promulgated by the Board for Licensing Health Care Facilities as a mandatory form shall serve as the Universal DNR according to these rules.~~

~~(71) Unusual Event. The abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient that is not related to a natural course of the patient's illness or underlying condition.~~

~~(72) Unusual Event Report. A report form designated by the department to be used for reporting an unusual event.~~

(~~73~~70) Water Treatment. The process of treating water used for dialysis purposes in order to maintain a continuous water supply that meets AAMI (Association for the Advancement of Medical Instrumentation) standards.

Authority: *T.C.A. §§4-5-202, 4-5-204, 39-11-106, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-224, and 68-11-1802.* ***Administrative History:*** *Original rule filed April 22, 2003; effective July 6, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendments filed December 15, 2005; effective February 28, 2006. Amendment filed February 7, 2007; effective April 23, 2007. Amendment filed December 9, 2010 to have been effective March 9, 2011 was stayed for 28 days by the Government Operations Committee; new effective date March 29, 2011.*

1200-08-32-.02 LICENSING PROCEDURES.

(Rule 1200-08-32-.10, continued)

another state, the facility must notify in writing all public health agencies with jurisdiction that the location is being used for management of the facility's waste. Waste shipped off-site must be packaged in accordance with applicable federal and state requirements. Waste transported to a sanitary landfill in this state must meet the requirements of current rules of the Department of Environment and Conservation.

(10) All garbage, trash and other non-infectious waste shall be stored and disposed of in a manner that shall not permit the transmission of disease, create a nuisance, provide a breeding place for insects and rodents, or constitute a safety hazard. All containers for waste shall be water tight, constructed of easily cleanable material and shall be kept on elevated platforms.

Authority: *T.C.A. §§4-5-202 through 4-5-206, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed April 22, 2003; effective July 6, 2003.*

1200-08-32-.11 RECORDS AND REPORTS.

(1) The renal dialysis clinic shall report each case of communicable disease to the local county health officer in the manner provided by existing regulations. Failure to report a communicable disease may result in disciplinary action, including revocation of the facility's license.

~~(2) Unusual events shall be reported by the facility to the Department of Health in a format designed by the Department within seven (7) business days of the date of the identification of the abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient.~~

~~(a) The following represent circumstances that could result in an unusual event that is an unexpected occurrence or accident resulting in death, life threatening or serious injury to a patient, not related to a natural course of the patient's illness or underlying condition. The circumstances that could result in an unusual event include, but are not limited to:~~

~~1. medication errors;~~

~~2. aspiration in a non-intubated patient related to conscious/moderate sedation;~~

~~3. intravascular catheter related events including necrosis or infection requiring repair or intravascular catheter related pneumothorax;~~

~~4. volume overload leading to pulmonary edema;~~

~~5. blood transfusion reactions, use of wrong type of blood and/or delivery of blood to the wrong patient;~~

~~6. perioperative/periprocedural related complication(s) that occur within 48 hours of the operation or the procedure, including a procedure which results in any new central neurological deficit or any new peripheral neurological deficit with motor weakness;~~

~~7. burns of a second or third degree;~~

~~8. falls resulting in radiologically proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage, and/or internal trauma, but does not include fractures resulting from pathological conditions;~~

(Rule 1200-08-82-.11, continued)

9. procedure related incidents, regardless of setting and within thirty (30) days of the procedure and includes readmissions, which include:

(i) procedure related injury requiring repair or removal of an organ;

(ii) hemorrhage;

(iii) displacement, migration or breakage of an implant, device, graft or drain;

(iv) post operative wound infection following clean or clean/contaminated case;

(v) any unexpected operation or reoperation related to the primary procedure;

(vi) hysterectomy in a pregnant woman;

(vii) ruptured uterus;

(viii) circumcision;

(ix) incorrect procedure or incorrect treatment that is invasive;

(x) wrong patient/wrong site surgical procedure;

(xi) unintentionally retained foreign body;

(xii) loss of limb or organ, or impairment of limb if the impairment is present at discharge or for at least two (2) weeks after occurrence;

(xiii) criminal acts;

(xiv) suicide or attempted suicide;

(xv) elopement from the facility;

(xvi) infant abduction, or infant discharged to the wrong family;

(xvii) adult abduction;

(xviii) rape;

(xix) patient altercation;

(xx) patient abuse, patient neglect, or misappropriation of resident/patient funds;

(xxi) restraint related incidents; or

(xxii) poisoning occurring within the facility.

(b) Specific incidents that might result in a disruption of the delivery of health care services at the facility shall also be reported to the department, on the unusual event form, within seven (7) days after the facility learns of the incident. These specific incidents include the following:

1. strike by the staff at the facility;

2. external disaster impacting the facility;

(Rule 1200-08-82-.11, continued)

3. disruption of any service vital to the continued safe operation of the facility or to the health and safety of its patients and personnel; and

4. fires at the facility which disrupt the provision of patient care services or cause harm to patients or staff, or which are reported by the facility to any entity, including but not limited to a fire department, charged with preventing fires.

(c) For health services provided in a "home" setting, only those unusual events actually witnessed or known by the person delivering health care services are required to be reported.

(d) Within forty (40) days of the identification of the event, the facility shall file with the department a corrective action report for the unusual event reported to the department. The department's approval of a Corrective Action Report will take into consideration whether the facility utilized an analysis in identifying the most basic or causal factor(s) that underlie variation in performance leading to the unusual event by (a) determining the proximate cause of the unusual event, (b) analyzing the systems and processes involved in the unusual event, (c) identifying possible common causes, (d) identifying potential improvements, and (e) identifying measures of effectiveness. The corrective action report shall either: (1) explain why a corrective action report is not necessary; or (2) detail the actions taken to correct any error identified that contributed to the unusual event or incident, the date the corrections were implemented, how the facility will prevent the error from recurring in the future and who will monitor the implementation of the corrective action plan.

(e) The department shall approve in writing, the corrective action report if the department is satisfied that the corrective action plan appropriately addresses errors that contributed to the unusual event and takes the necessary steps to prevent the recurrence of the errors. If the department fails to approve the corrective action report, then the department shall provide the facility with a list of actions that the department believes are necessary to address the errors. The facility shall be offered an informal meeting with the Commissioner or the Commissioner's representative to attempt to resolve any disagreement over the corrective action report. If the department and the facility fail to agree on an appropriate corrective action plan, then the final determination on the adequacy of the corrective action report shall be made by the Board after a contested case hearing.

(f) The event report reviewed or obtained by the department shall be confidential and not subject to discovery, subpoena or legal compulsion for release to any person or entity, nor shall the report be admissible in any civil or administrative proceeding other than a disciplinary proceeding by the department or the appropriate regulatory board. The report is not discoverable or admissible in any civil or administrative action except that information in any such report may be transmitted to an appropriate regulatory agency having jurisdiction for disciplinary or license sanctions against the impacted facility. The department must reveal upon request its awareness that a specific event or incident has been reported.

(g) The department shall have access to facility records as allowed in Title 68, Chapter 11, Part 3. The department may copy any portion of a facility medical record relating to the reported event unless otherwise prohibited by rule or statute. This section does not change or affect the privilege and confidentiality provided by T.C.A. §63-6-219.

(h) The department, in developing the unusual event report form, shall establish an event occurrence code that categorizes events or specific incidents by the examples set forth above in (a) and (b). If an event or specific incident fails to come within these examples,

(Rule 1200-08-82-.11, continued)

~~it shall be classified as "other" with the facility explaining the facts related to the event or incident.~~

~~(i) This does not preclude the department from using information obtained under these rules in a disciplinary action commenced against a facility, or from taking a disciplinary action against a facility. Nor does this preclude the department from sharing such information with any appropriate governmental agency charged by federal or state law with regulatory oversight of the facility. However, all such information must at all times be maintained as confidential and not available to the public. Failure to report an unusual event, submit a corrective action report, or comply with a plan of correction as required herein may be grounds for disciplinary action pursuant to T.C.A. §68-11-207.~~

~~(j) The affected patient and/or the patient's family, as may be appropriate, shall also be notified of the event or incident by the facility.~~

~~(k) During the second quarter of each year, the Department shall provide the Board an aggregate report summarizing by type the number of unusual events and incidents reported by facilities to the Department for the preceding calendar year.~~

~~(l) The Department shall work with representatives of facilities subject to these rules, and other interested parties, to develop recommendations to improve the collection and assimilation of specific aggregate health care data that, if known, would track health care trends over time and identify system-wide problems for broader quality improvement. The goal of such recommendations should be to better coordinate the collection of such data, to analyze the data, to identify potential problems and to work with facilities to develop best practices to remedy identified problems. The Department shall prepare and issue a report regarding such recommendations.~~

(2) The renal dialysis clinic shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

(3) The renal dialysis clinic shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the ESRD or to the health and safety of its patients and personnel; and

(d) Fires at the renal dialysis clinic that disrupt the provision of patient care services or cause harm to the patients or staff, or that are reported by the facility to any entity, including but not limited to a fire department charged with preventing fires.

(~~3~~4) The renal dialysis clinic shall retain legible copies of the following records and reports for thirty-six months following their issuance. They shall be maintained in a single file and shall be made available for inspection during normal business hours to any person who requests to view them:

(a) Local fire safety inspections;

(b) Local building code inspections, if any;

(c) Fire marshal reports;

(Rule 1200-08-82-.11, continued)

(d) Department licensure and fire safety inspections and surveys;

(e) Federal Health Care Financing Administration surveys and inspections, if any;

(f) Orders of the Commissioner or Board, if any;

(g) Comptroller of the Treasury's audit reports and findings, if any; and,

(h) Maintenance records of all safety equipment.

(45) Copies of the records and reports listed above, with the exception of patient records, shall be maintained in a location convenient to the public and, during normal business hours. They shall be made available for inspection by any person who requests to view them. Each patient and/or person assuming any financial responsibility for a patient shall be fully informed, before or at the time of admission, of the availability of these reports.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-210, and 68-11-211.* ***Administrative History:*** *Original rule filed April 22, 2003; effective July 6, 2003.*

1200-08-32-.12 PATIENT RIGHTS.

(1) Each patient has at least the following rights:

(a) To privacy in treatment and personal care;

(b) To be free from mental and physical abuse. Should this right be violated, the facility must notify the department within seven (7) business days and the Tennessee Department of Human Services, Adult Protective Services immediately as required by T.C.A. §71-6-101 et seq;

(c) To refuse treatment. The patient must be informed of the consequences of that decision. The refusal and its reason must be reported to the physician and documented in the medical record;

(d) To refuse experimental treatment and drugs. The patient's or health care decision maker's written consent for participation in research must be obtained and retained in his or her medical record;

(e) To have their records kept confidential and private. Written consent by the patient must be obtained prior to release of information except to persons authorized by law. If the patient lacks capacity, written consent is required from the patient's health care decision maker. The renal dialysis clinic must have policies to govern access and duplication of the patient's record;

(f) To have appropriate assessment and management of pain; and

(g) To be involved in all aspects of their care.

(2) Each patient has a right to self-determination, which encompasses the right to make choices regarding life-sustaining treatment (including resuscitative services). This right of self-determination may be effectuated by an advance directive.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed April 22, 2003; effective July 6, 2003. Amendment filed December 15, 2005; effective February 28, 2006.*

1200-08-32-.13 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING.

(1) Pursuant to this Rule, each end stage renal dialysis clinic shall maintain and establish policies and procedures governing the designation of a health care decision-maker for making health care decisions for a patient who is incompetent or who lacks capacity, including but not limited to allowing the withholding of CPR measures from individual patients. An adult or emancipated minor may give an individual instruction. The instruction may be oral or written. The instruction may be limited to take effect only if a specified condition arises.

(2) An adult or emancipated minor may execute an advance directive for health care. The advance directive may authorize an agent to make any health care decision the patient could have made while having capacity, or may limit the power of the agent, and may include individual instructions. The effect of an advance directive that makes no limitation on the agent's authority shall be to authorize the agent to make any health care decision the patient could have made while having capacity.

(3) The advance directive shall be in writing, signed by the patient, and shall either be notarized or witnessed by two (2) witnesses. Both witnesses shall be competent adults, and neither of

(Rule 1200-08-32-.13, continued)

them may be the agent. At least one (1) of the witnesses shall be a person who is not related to the patient by blood, marriage, or adoption and would not be entitled to any portion of the estate of the patient upon the death of the patient. The advance directive shall contain a clause that attests that the witnesses comply with the requirements of this paragraph.

(4) Unless otherwise specified in an advance directive, the authority of an agent becomes effective only upon a determination that the patient lacks capacity, and ceases to be effective upon a determination that the patient has recovered capacity.

~~(5) A facility shall use the mandatory advance directive form that meets the requirements of the Tennessee Health Care Decisions Act and has been developed and issued by the Board for Licensing Health Care Facilities.~~

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

(6) A determination that a patient lacks or has recovered capacity, or that another condition exists that affects an individual instruction or the authority of an agent shall be made by the designated physician, who is authorized to consult with such other persons as he or she may deem appropriate.

(7) An agent shall make a health care decision in accordance with the patient's individual instructions, if any, and other wishes to the extent known to the agent. Otherwise, the agent shall make the decision in accordance with the patient's best interest. In determining the patient's best interest, the agent shall consider the patient's personal values to the extent known.

(8) An advance directive may include the individual's nomination of a court-appointed guardian.

(9) A health care facility shall honor an advance directive that is executed outside of this state by a nonresident of this state at the time of execution if that advance directive is in compliance with the laws of Tennessee or the state of the patient's residence.

(10) No health care provider or institution shall require the execution or revocation of an advance directive as a condition for being insured for, or receiving, health care.

(11) Any living will, durable power of attorney for health care, or other instrument signed by the individual, complying with the terms of Tennessee Code Annotated, Title 32, Chapter 11, and a durable power of attorney for health care complying with the terms of Tennessee Code Annotated, Title 34, Chapter 6, Part 2, shall be given effect and interpreted in accord with those respective acts. Any advance directive that does not evidence an intent to be given effect under those acts but that complies with these regulations may be treated as an advance directive under these regulations.

(12) A patient having capacity may revoke the designation of an agent only by a signed writing or by personally informing the supervising health care provider.

(13) A patient having capacity may revoke all or part of an advance directive, other than the designation of an agent, at any time and in any manner that communicates an intent to revoke.

(14) A decree of annulment, divorce, dissolution of marriage, or legal separation revokes a previous designation of a spouse as an agent unless otherwise specified in the decree or in an advance directive.

(Rule 1200-08-32-.13, continued)

(15) An advance directive that conflicts with an earlier advance directive revokes the earlier directive to the extent of the conflict.

(16) Surrogates.

(a) An adult or emancipated minor may designate any individual to act as surrogate by personally informing the supervising health care provider. The designation may be oral or written.

(b) A surrogate may make a health care decision for a patient who is an adult or emancipated minor if and only if:

1. the patient has been determined by the designated physician to lack capacity, and

2. no agent or guardian has been appointed, or

3. the agent or guardian is not reasonably available.

(c) In the case of a patient who lacks capacity, the patient's surrogate shall be identified by the supervising health care provider and documented in the current clinical record of the facility at which the patient is receiving health care.

(d) The patient's surrogate shall be an adult who has exhibited special care and concern for the patient, who is familiar with the patient's personal values, who is reasonably available, and who is willing to serve.

(e) Consideration may be, but need not be, given in order of descending preference for service as a surrogate to:

1. the patient's spouse, unless legally separated;

2. the patient's adult child;

3. the patient's parent;

4. the patient's adult sibling;

5. any other adult relative of the patient; or

6. any other adult who satisfies the requirements of 1200-08-32-.13(16)(d).

(f) No person who is the subject of a protective order or other court order that directs that person to avoid contact with the patient shall be eligible to serve as the patient's surrogate.

(g) The following criteria shall be considered in the determination of the person best qualified to serve as the surrogate:

1. Whether the proposed surrogate reasonably appears to be better able to make decisions either in accordance with the known wishes of the patient or in accordance with the patient's best interests;

2. The proposed surrogate's regular contact with the patient prior to and during the incapacitating illness;

(Rule 1200-08-32-.13, continued)

3. The proposed surrogate's demonstrated care and concern;

4. The proposed surrogate's availability to visit the patient during his or her illness; and

5. The proposed surrogate's availability to engage in face-to-face contact with health care providers for the purpose of fully participating in the decision-making process.

(h) If the patient lacks capacity and none of the individuals eligible to act as a surrogate under 1200-08-32-.13(16)(c) thru 1200-08-32-.13(16)(g) is reasonably available, the designated physician may make health care decisions for the patient after the designated physician either:

1. Consults with and obtains the recommendations of a facility's ethics mechanism or standing committee in the facility that evaluates health care issues; or

2. Obtains concurrence from a second physician who is not directly involved in the patient's health care, does not serve in a capacity of decision-making, influence, or responsibility over the designated physician, and is not under the designated physician's decision-making, influence, or responsibility.

(i) In the event of a challenge, there shall be a rebuttable presumption that the selection of the surrogate was valid. Any person who challenges the selection shall have the burden of proving the invalidity of that selection.

(j) A surrogate shall make a health care decision in accordance with the patient's individual instructions, if any, and other wishes to the extent known to the surrogate. Otherwise, the surrogate shall make the decision in accordance with the surrogate's determination of the patient's best interest. In determining the patient's best interest, the surrogate shall consider the patient's personal values to the extent known to the surrogate.

(k) A surrogate who has not been designated by the patient may make all health care decisions for the patient that the patient could make on the patient's own behalf, except that artificial nutrition and hydration may be withheld or withdrawn for a patient upon a decision of the surrogate only when the designated physician and a second independent physician certify in the patient's current clinical records that the provision or continuation of artificial nutrition or hydration is merely prolonging the act of dying and the patient is highly unlikely to regain capacity to make medical decisions.

(l) Except as provided in 1200-08-32-.13(16)(m):

1. Neither the treating health care provider nor an employee of the treating health care provider, nor an operator of a health care institution nor an employee of an operator of a health care institution may be designated as a surrogate; and

2. A health care provider or employee of a health care provider may not act as a surrogate if the health care provider becomes the patient's treating health care provider.

(m) An employee of the treating health care provider or an employee of an operator of a health care institution may be designated as a surrogate if:

1. the employee so designated is a relative of the patient by blood, marriage, or adoption; and

(Rule 1200-08-32-.13, continued)

2. the other requirements of this section are satisfied.

(n) A health care provider may require an individual claiming the right to act as surrogate for a patient to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(17) Guardian.

(a) A guardian shall comply with the patient's individual instructions and may not revoke the patient's advance directive absent a court order to the contrary.

(b) Absent a court order to the contrary, a health care decision of an agent takes precedence over that of a guardian.

(c) A health care provider may require an individual claiming the right to act as guardian for a patient to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(18) A designated physician who makes or is informed of a determination that a patient lacks or has recovered capacity, or that another condition exists which affects an individual instruction or the authority of an agent, guardian, or surrogate, shall promptly record the determination in the patient's current clinical record and communicate the determination to the patient, if possible, and to any person then authorized to make health care decisions for the patient.

(19) Except as provided in 1200-08-32-.13(20) thru 1200-08-32-.13(22), a health care provider or institution providing care to a patient shall:

(a) comply with an individual instruction of the patient and with a reasonable interpretation of that instruction made by a person then authorized to make health care decisions for the patient; and

(b) comply with a health care decision for the patient made by a person then authorized to make health care decisions for the patient to the same extent as if the decision had been made by the patient while having capacity.

(20) A health care provider may decline to comply with an individual instruction or health care decision for reasons of conscience.

(21) A health care institution may decline to comply with an individual instruction or health care decision if the instruction or decision is:

(a) contrary to a policy of the institution which is based on reasons of conscience, and

(b) the policy was timely communicated to the patient or to a person then authorized to make health care decisions for the patient.

(22) A health care provider or institution may decline to comply with an individual instruction or health care decision that requires medically inappropriate health care or health care contrary to generally accepted health care standards applicable to the health care provider or institution.

(23) A health care provider or institution that declines to comply with an individual instruction or health care decision pursuant to 1200-08-32-.13(20) thru 1200-08-32-.13(22) shall:

(Rule 1200-08-32-.13, continued)

(a) promptly so inform the patient, if possible, and any person then authorized to make health care decisions for the patient;

(b) provide continuing care to the patient until a transfer can be effected or until the determination has been made that transfer cannot be effected;

(c) unless the patient or person then authorized to make health care decisions for the patient refuses assistance, immediately make all reasonable efforts to assist in the transfer of the patient to another health care provider or institution that is willing to comply with the instruction or decision; and

(d) if a transfer cannot be effected, the health care provider or institution shall not be compelled to comply.

(24) Unless otherwise specified in an advance directive, a person then authorized to make health care decisions for a patient has the same rights as the patient to request, receive, examine, copy, and consent to the disclosure of medical or any other health care information.

(25) A health care provider or institution acting in good faith and in accordance with generally accepted health care standards applicable to the health care provider or institution is not subject to civil or criminal liability or to discipline for unprofessional conduct for:

(a) complying with a health care decision of a person apparently having authority to make a health care decision for a patient, including a decision to withhold or withdraw health care;

(b) declining to comply with a health care decision of a person based on a belief that the person then lacked authority; or

(c) complying with an advance directive and assuming that the directive was valid when made and had not been revoked or terminated.

(26) An individual acting as an agent or surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for health care decisions made in good faith.

(27) A person identifying a surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for such identification made in good faith.

(28) A copy of a written advance directive, revocation of an advance directive, or designation or disqualification of a surrogate has the same effect as the original.

(29) The withholding or withdrawal of medical care from a patient in accordance with the provisions of the Tennessee Health Care Decisions Act shall not, for any purpose, constitute a suicide, euthanasia, homicide, mercy killing, or assisted suicide.

(30) Universal Do Not Resuscitate Order (DNR).

~~(a) The Physicians Order for Scope of Treatment (POST) form, a mandatory form meeting the provisions of the Health Care Decision Act and approved by the Board for Licensing Health Care Facilities, shall be used as the Universal Do Not Resuscitate Order by all facilities. A universal do not resuscitate order (DNR) may be used by a physician for his/her patient with whom he/she has a physician/patient relationship, but only:~~

~~1. with the consent of the patient; or~~

(Rule 1200-08-32-.13, continued)

~~2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or~~

~~3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.~~

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do Not Resuscitate Order may be used by a physician for a patient with whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

(b) If the patient is an adult who is capable of making an informed decision, the patient's expression of the desire to be resuscitated in the event of cardiac or respiratory arrest shall revoke a universal do not resuscitate order. If the patient is a minor or is otherwise incapable of making an informed decision, the expression of the desire that the patient be resuscitated by the person authorized to consent on the patient's behalf shall revoke a universal do not resuscitate order.

(c) Universal do not resuscitate orders shall remain valid and in effect until revoked. Qualified emergency medical services personnel, and licensed health care practitioners in any facility, program or organization operated or licensed by the board for licensing health care facilities or by the department of mental health and developmental disabilities or operated, licensed, or owned by another state agency are authorized to follow universal do not resuscitate orders.

(d) Nothing in these rules shall authorize the withholding of other medical interventions, such as intravenous fluids, oxygen, or other therapies deemed necessary to provide comfort care or to alleviate pain.

~~(e) If a person with a universal do not resuscitate order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the universal do not resuscitate order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the universal do not resuscitate order accompanies the patient in transport to the receiving~~

(Rule 1200-08-32-.13, continued)

~~health care facility. Upon admission, the receiving facility shall make the universal do not resuscitate order a part of the patient's record.~~

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

(f) This section shall not prevent, prohibit, or limit a physician from issuing a written order, other than a universal do not resuscitate order, not to resuscitate a patient in the event of cardiac or respiratory arrest in accordance with accepted medical practices.

(g) Valid do not resuscitate orders or emergency medical services do not resuscitate orders issued before July 1, 2004, pursuant to the then-current law, shall remain valid and shall be given effect as provided.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-224, 68-11-1801 through 68-11-1815.* ***Administrative History:*** *Original rule filed April 22, 2003; effective July 6, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Repeal and new rule filed December 15, 2005; effective February 28, 2006. Amendment filed February 7, 2007; effective April 23, 2007.*

1200-08-32-.14 DISASTER PREPAREDNESS.

(1) The administration of every facility shall have in effect and available for all supervisory personnel and staff, written copies of the following required disaster plans, for the protection of all persons in the event of fire and other emergencies, for evacuation to areas of refuge and /or evacuation from the building. A detailed log with staff signatures of training received shall be maintained. All employees shall be trained annually as required in the following plans and shall be kept informed with respect to their duties under the plans. A copy of the plans shall be readily available at all times in the telephone operator's position or at the security center. Each of the following plans shall be exercised annually prior to the month listed in each plan:

(a) Fire Safety Procedures Plan (to be exercised at any time during the year) shall include:

1. Minor fires;

2. Major fires;

3. Fighting the fire;

4. Evacuation procedures; and

5. Staff functions by department and job assignment.

(b) Tornado/Severe Weather Procedures Plan shall include:

1. Staff duties by department and job assignment; and

2. Evacuation procedures.

RULES
OF
DEPARTMENT OF HEALTH
BOARD FOR LICENSING HEALTH CARE FACILITIES

CHAPTER 1200-08-34
STANDARDS FOR HOME CARE ORGANIZATIONS
PROVIDING PROFESSIONAL SUPPORT SERVICES

TABLE OF CONTENTS

1200-08-34-.01 DEFINITIONS.

(1) Administrator. A person who establishes policies and procedures and is responsible for the activities of the agency and its staff. This person may be a physician, registered nurse, therapist, or a person with at least one (1) year experience in a health or disability related field. The administrator of a home care organization may serve as both a home health agency and professional support service agency administrator if both agencies are owned by the same corporation or legal entity.

(2) Adult. An individual who has capacity and is at least 18 years of age.

(3) Advance Directive. An individual instruction or a written statement relating to the subsequent provision of health care for the individual, including, but not limited to, a living will or a durable power of attorney for health care.

(4) Agency. A home care organization providing professional support services.

(5) Agent. An individual designated in an advance directive for health care to make a health care decision for the individual granting the power.

~~(6) Analysis. A process for identifying the most basic or causal factor or factors that underlie variation in performance leading to an unusual event. The analysis must contain the following analytical processes: the proximate cause of the unusual event, an analysis of systems and processes involved in the unusual event, identification of possible common causes, identification of potential improvements, the plan of correction or action plan, and measures of effectiveness.~~

(~~7~~6) Board. The Tennessee Board for Licensing Health Care Facilities.

(~~8~~7) Capacity. An individual's ability to understand the significant benefits, risks, and alternatives to proposed health care and to make and communicate a health care decision. These regulations do not affect the right of a consumer to make health care decisions while having the capacity to do so. A consumer shall be presumed to have capacity to make a health care decision, to give or revoke an advance directive, and to designate or disqualify a surrogate. Any person who challenges the capacity of a consumer shall have the burden of proving lack of capacity.

(Rule 1200-08-34-.01, continued)

(~~9~~8) Clinical Note. A written and dated notation containing a consumer assessment, responses to medications, treatments, services, any changes in condition and signed by a health team member who made contact with the consumer.

(~~10~~9) Commissioner. The Commissioner of the Tennessee Department of Health or his or her authorized representative.

(~~11~~10) Competent. A consumer who has capacity.

(~~12~~11) Comprehensive Nursing assessment. An assessment conducted by a registered nurse which consists of four parts: completion of a Physical Status Review (PSR); consumer and family history; identification of health concerns, functional abilities, activities of daily living; and, completion of a head to toe physical assessment.

(~~13~~12) Consumer. Any person with a primary diagnosis of mental retardation or developmental disability served through the Division of Mental Retardation Services or the Department of Mental Health and Developmental Disabilities in need of nursing, occupational, physical or speech therapy through a professional support service agency.

~~(14) Corrective Action Plan/Report. A report filed with the department by the agency after reporting an unusual event. The report must consist of the following:~~

~~(a) the action(s) implemented to prevent the reoccurrence of the unusual event,~~

~~(b) the time frames for the action(s) to be implemented,~~

~~(c) the person(s) designated to implement and monitor the action(s), and~~

~~(d) the strategies for the measurements of effectiveness to be established.~~

(~~15~~13) Department. The Tennessee Department of Health.

(~~16~~14) Designated Physician. A physician designated by an individual or the individual's agent, guardian, or surrogate, to have primary responsibility for the individual's health care or, in the absence of a designation or if the designated physician is not reasonably available, a physician who undertakes such responsibility.

(~~17~~15) Emancipated Minor. Any minor who is or has been married or has by court order or otherwise been freed from the care, custody and control of the minor's parents.

(~~18~~16) Emergency Responder. A paid or volunteer firefighter, law enforcement officer, or other public safety official or volunteer acting within the scope of his or her proper function under law or rendering emergency care at the scene of an emergency.

(~~19~~17) Guardian. A judicially appointed guardian or conservator having authority to make a health care decision for an individual.

(~~20~~18) Hazardous Waste. Materials whose handling, use, storage and disposal are governed by local, state or federal regulations.

(~~21~~19) Health Care. Any care, treatment, service or procedure to maintain, diagnose, treat, or otherwise affect an individual's physical or mental condition, and includes medical care as defined in T.C.A. §32-11-103(5).

(~~22~~20) Health Care Decision. Consent, refusal of consent or withdrawal of consent to health care.

(Rule 1200-08-34-.01, continued)

(~~23~~21) Health Care Decision-maker. In the case of a consumer who lacks capacity, the consumer's health care decision-maker is one of the following: the consumer's health care agent as specified in an advance directive, the consumer's court-appointed guardian or conservator with health care decision-making authority, the consumer's surrogate as determined pursuant to Rule 1200-08-34-.13 or T.C.A. §33-3-220, the designated physician pursuant to these Rules or in the case of a minor child, the person having custody or legal guardianship.

(~~24~~22) Health Care Institution. A health care institution as defined in T.C.A. §68-11-1602.

(~~25~~23) Health Care Provider. A person who is licensed, certified or otherwise authorized or permitted by the laws of this state to administer health care in the ordinary course of business or practice of a profession.

(~~26~~24) Individual instruction. An individual's direction concerning a health care decision for the individual.

(~~27~~25) Individual Support Plan (ISP). The document resulting from a process of person-centered planning. The ISP describes in detail the person, including his/her vision for his/her future, preferences, non-negotiables, and other information required to support the person in daily life. The ISP contains outcomes to be achieved with the assistance of the person's Circle of Support that relate to the person's vision for the future. The ISP is written upon a person's enrollment in Department of Mental Retardation Services and updated thereafter as changes occur in the individual's life, or at least annually.

(~~28~~26) Infectious Waste. Solid or liquid wastes which contain pathogens with sufficient virulence and quantity such that exposure to the waste by a susceptible host could result in an infectious disease.

(~~29~~27) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(~~30~~28) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.

(~~31~~29) Life Threatening or Serious Injury. Injury requiring the consumer to undergo significant additional diagnostic or treatment measures.

(~~32~~30) Medical Record. Medical histories, records, reports, clinical notes, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries and other written electronic, or graphic data prepared, kept, made or maintained in an agency that pertains to confinement or services rendered to consumers. The medical record shall meet the standards established in the contractual agreement between the state agency financially responsible for services to individuals with mental retardation or developmental disabilities.

(~~33~~31) Medically Inappropriate Treatment. Resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the consumer or other medical or surgical treatments to achieve the expressed goals of the informed consumer. In the case of the incompetent consumer, the consumer's representative expresses the goals of the consumer.

(~~34~~32) Occupational Therapist. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~35~~33) Occupational Therapy Assistant. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(Rule 1200-08-34-.01, continued)

(~~36~~34) Patient/Consumer Abuse. Patient/consumer neglect, intentional infliction of pain, injury, or mental anguish. Patient/consumer abuse includes the deprivation of services by a caretaker which are necessary to maintain the health and welfare of a patient or consumer; however, the withholding of authorization for or provision of medical care to any terminally ill person who has executed an irrevocable living will in accordance with the Tennessee Right to Natural Death Law, or other applicable state law, if the provision of such medical care would conflict with the terms of such living will shall not be deemed "patient/consumer abuse" for purposes of these rules.

(~~37~~35) Person. An individual, corporation, estate, trust, partnership, association, joint venture, government, governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.

(~~38~~36) Personally Informing. A communication by any effective means from the consumer directly to a health care provider.

(~~39~~37) Physical Status Report (PSR). An instrument used by a registered nurse or other designated professional staff to determine level of risk and define the required health services and supports.

(~~40~~38) Physical Therapist. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~41~~39) Physical Therapy Assistant. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~42~~40) Physician. An individual authorized to practice medicine or osteopathy under Tennessee Code Annotated, Title 63, Chapters 6 or 9.

(~~43~~41) Plan of Care. Health care plan resulting from the comprehensive nursing assessment and/or therapy plan identifying the need for nursing, physical, occupational, or speech therapy for consumers of professional support services. The plan shall meet the standards established in the contractual agreement between the state agency financially responsible for services to individuals with mental retardation or developmental disabilities.

(~~44~~42) Power of Attorney for Health Care. The designation of an agent to make health care decisions for the individual granting the power under T.C.A. Title 34, Chapter 6, Part 2.

(~~45~~43) Professional Support Services. Nursing, occupational, physical or speech therapy services provided to individuals with mental retardation or developmental disabilities pursuant to a contract with the state agency financially responsible for such services.

(~~46~~44) Qualified Emergency Medical Service Personnel. Includes, but shall not be limited to, emergency medical technicians, paramedics, or other emergency services personnel, providers, or entities acting within the usual course of their professions, and other emergency responders.

(~~47~~45) Reasonably Available. Readily able to be contacted without undue effort and willing and able to act in a timely manner considering the urgency of the consumer's health care needs. Such availability shall include, but not be limited to, availability by telephone.

(~~48~~46) Registered Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(~~49~~47) Shall or Must. Compliance is mandatory.

(Rule 1200-08-34-.01, continued)

(~~50~~48) Site Code. An approved location from which the professional support services may be provided as deemed by the Department of Mental Retardation Services with written notice provided to the Department of Health by the professional support service agency for each site code approved for such agency.

(~~51~~49) Speech Language Pathologist. A person currently licensed as such by the Tennessee Board of Communication Disorders and Sciences or, for purposes of these rules, a Speech Language Pathologist who is currently in their Clinical Fellowship Year.

(~~52~~50) State. A state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.

(~~53~~51) Supervising Health Care Provider. The designated physician or, if there is no designated physician or the designated physician is not reasonably available, the health care provider who has undertaken primary responsibility for an individual's health care.

(~~54~~52) Supervision. Authoritative procedural guidance by a qualified person for the accomplishment of a function or activity with initial direction and periodic inspection of the actual act of accomplishing the function or activity. Periodic supervision must be provided if the person is not a licensed or certified assistant, unless otherwise provided in accordance with these rules.

(~~55~~53) Surrogate. An individual, other than a consumer's agent or guardian, authorized to make a health care decision for the consumer.

(~~56~~54) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the consumer.

~~(57) Universal Do Not Resuscitate Order. A written order that applies regardless of the treatment setting and that is signed by the patient's physician which states that in the event the patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The Physician Order for Scope of Treatment (POST) form promulgated by the Board for Licensing Health Care Facilities as a mandatory form shall serve as the Universal DNR according to these rules.~~

(55) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

~~(58) Unusual Event. The abuse of a consumer or an unexpected occurrence or accident that results in death, life threatening or serious injury to a consumer that is not related to a natural course of the consumer's illness or underlying condition.~~

~~(59) Unusual Event Report. A report form designated by the department to be used for reporting an unusual event.~~

Authority: *T.C.A. §§4-5-202, 4-5-204, 39-11-106, 68-11-201, 68-11-202, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-224, and 68-11-1802.* ***Administrative History:*** *Original rule filed January 24, 2003; effective April 9, 2003. Amendments filed December 2, 2005; effective February 15, 2006. Amendment filed February 7, 2007; effective April 23, 2007.*

1200-08-34-.02 LICENSING PROCEDURES.

(Rule 1200-08-34-.10, continued)

(a) Contaminated sharps must be directly placed in leakproof, rigid and puncture-resistant containers which must then be tightly sealed.

(b) Infectious and hazardous waste must be secured in fastened plastic bags before placement in a garbage can with other household waste.

(c) Reusable containers for infectious waste must be thoroughly sanitized each time they are emptied, unless the surfaces of the containers have been completely protected from contamination by disposable liners or other devices removed with the waste.

(4) After packaging, waste must be handled, transported and stored by methods ensuring containment and preserving of the integrity of the packaging, including the use of secondary containment where necessary.

(5) Waste must be stored in a manner which preserves the integrity of the packaging, inhibits rapid microbial growth and putrefaction, and minimizes the potential of exposure or access by unknowing persons. Waste must be stored in a manner and location which affords protection from animals, precipitation, wind and direct sunlight, does not present a safety hazard, does not provide a breeding place or food source for insects or rodents and does not create a nuisance.

(6) In the event of spills, ruptured packaging, or other incidents where there is a loss of containment of waste, the agency must ensure that proper actions are immediately taken to:

(a) Isolate the area;

(b) Repackage all spilled waste and contaminated debris in accordance with the requirements of this rule; and,

(c) Sanitize all contaminated equipment and surfaces appropriately.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, and 68-11-209.* ***Administrative History:*** *Original rule filed January 24, 2003; effective April 9, 2003.*

1200-08-34-.11 RECORDS AND REPORTS.

(1) The agency shall retain legible copies of the following records and reports for thirty-six (36) months following their issuance. They shall be maintained in a single file and shall be made available for inspection during normal business hours to any person who requests to view them:

(a) Department licensure and fire safety inspections and surveys;

(b) Centers for Medicare and Medicaid Services (CMS) surveys and inspections, if any;

(c) Orders of the Commissioner or Board, if any; and

(d) Comptroller of the Treasury's audit report and finding, if any.

~~(2) Unusual events shall be reported by the agency to the Department of Health in a format designed by the Department within seven (7) business days of the date of the identification of the abuse of a consumer or an unexpected occurrence or accident that results in death, life threatening or serious injury to a consumer.~~

(Rule 1200-08-34-.11, continued)

~~(a) The following represent circumstances that could result in an unusual event that is an unexpected occurrence or accident resulting in death, life threatening or serious injury to a consumer, not related to a natural course of the consumer's illness or underlying condition. The circumstances that could result in an unusual event include, but are not limited to:~~

~~1. medication errors;~~

~~2. aspiration in a non-intubated consumer related to conscious/moderate sedation;~~

~~3. intravascular catheter related events including necrosis or infection requiring repair or intravascular catheter related pneumothorax;~~

~~4. volume overload leading to pulmonary edema;~~

~~5. blood transfusion reactions, use of wrong type of blood and/or delivery of blood to the wrong consumer;~~

~~6. perioperative/periprocedural related complication(s) that occur within 48 hours of the operation or the procedure, including a procedure which results in any new central neurological deficit or any new peripheral neurological deficit with motor weakness;~~

~~7. burns of a second or third degree;~~

~~8. falls resulting in radiologically proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage, and/or internal trauma, but does not include fractures resulting from pathological conditions; and~~

~~9. procedure related incidents, regardless of setting and within thirty (30) days of the procedure and includes readmissions, which include:~~

~~(i) procedure related injury requiring repair or removal of an organ;~~

~~(ii) hemorrhage;~~

~~(iii) displacement, migration or breakage of an implant, device, graft or drain;~~

~~(iv) post operative wound infection following clean or clean/contaminated case;~~

~~(v) any unexpected operation or re-operation related to the primary procedure;~~

~~(vi) hysterectomy in a pregnant woman;~~

~~(vii) ruptured uterus;~~

~~(viii) circumcision;~~

~~(ix) incorrect procedure or incorrect treatment that is invasive;~~

~~(x) wrong patient/wrong site surgical procedure;~~

~~(xi) unintentionally retained foreign body;~~

~~(xii) loss of limb or organ, or impairment of limb if the impairment is present at discharge or for at least two (2) weeks after occurrence;~~

(Rule 1200-08-34-.11, continued)

~~(xiii) criminal acts;~~

~~(xiv) suicide or attempted suicide;~~

~~(xv) elopement from the agency;~~

~~(xvi) infant abduction, or infant discharged to the wrong family;~~

~~(xvii) adult abduction;~~

~~(xviii) rape;~~

~~(xix) consumer altercation;~~

~~(xx) consumer abuse, consumer neglect, or misappropriation of consumer funds;~~

~~(xxi) restraint related incidents; or~~

~~(xxii) poisoning occurring within the agency.~~

~~(b) Specific incidents that might result in a disruption of the delivery of professional support services at the agency shall also be reported to the department, on the unusual event form, within seven (7) days after the agency learns of the incident. These specific incidents include the following:~~

~~1. strike by the staff at the agency;~~

~~2. external disaster impacting the agency;~~

~~3. disruption of any service vital to the continued safe operation of the agency or to the health and safety of its consumers and personnel; and~~

~~4. fires at the agency which disrupt the provision of consumer care services or cause harm to consumers or staff, or which are reported by the agency to any entity, including but not limited to a fire department, charged with preventing fires.~~

~~(c) For professional support services provided in a "home" setting, only those unusual events actually witnessed or known by the person delivering services are required to be reported.~~

~~(d) Within forty (40) days of the identification of the event, the agency shall file with the department a corrective action report for the unusual event reported to the department. The department's approval of a Corrective Action Report will take into consideration whether the agency utilized an analysis in identifying the most basic or casual factor(s) that underlie variation in performance leading to the unusual event by (a) determining the proximate cause of the unusual event, (b) analyzing the systems and processes involved in the unusual event, (c) identifying possible common causes, (d) identifying potential improvements, and (e) identifying measures of effectiveness. The corrective action report shall either: (1) explain why a corrective action report is not necessary; or (2) detail the actions taken to correct any error identified that contributed to the unusual event or incident, the date the corrections were implemented, how the agency will prevent the error from recurring in the future and who will monitor the implementation of the corrective action plan.~~

(Rule 1200-08-34-.11, continued)

(e) The department shall approve in writing, the corrective action report if the department is satisfied that the corrective action plan appropriately addresses errors that contributed to the unusual event and takes the necessary steps to prevent the recurrence of the errors. If the department fails to approve the corrective action report, then the department shall provide the agency with a list of actions that the department believes are necessary to address the errors. The agency shall be offered an informal meeting with the Commissioner or the Commissioner's representative to attempt to resolve any disagreement over the corrective action report. If the department and the agency fail to agree on an appropriate corrective action plan, then the final determination on the adequacy of the corrective action report shall be made by the Board after a contested case hearing.

(f) The event report reviewed or obtained by the department shall be confidential and not subject to discovery, subpoena or legal compulsion for release to any person or entity, nor shall the report be admissible in any civil or administrative proceeding other than a disciplinary proceeding by the department or the appropriate regulatory board. The report is not discoverable or admissible in any civil or administrative action except that information in any such report may be transmitted to an appropriate regulatory agency having jurisdiction for disciplinary or license sanctions against the impacted agency. The department must reveal upon request its awareness that a specific event or incident has been reported.

(g) The department shall have access to agency records as allowed in Title 68, Chapter 11, Part 3. The department may copy any portion of an agency medical record relating to the reported event unless otherwise prohibited by rule or statute. This section does not change or affect the privilege and confidentiality provided by T.C.A. §63-6-219.

(h) The department, in developing the unusual event report form, shall establish an event occurrence code that categorizes events or specific incidents by the examples set forth above in (a) and (b). If an event or specific incident fails to come within these examples, it shall be classified as "other" with the agency explaining the facts related to the event or incident.

(i) This does not preclude the department from using information obtained under these rules in a disciplinary action commenced against an agency, or from taking a disciplinary action against an agency. Nor does this preclude the department from sharing such information with any appropriate governmental agency charged by federal or state law with regulatory oversight of the agency. However, all such information must at all times be maintained as confidential and not available to the public. Failure to report an unusual event, submit a corrective action report, or comply with a plan of correction as required herein may be grounds for disciplinary action pursuant to T.C.A. §68-11-207.

(j) The affected consumer and/or the consumer's family, as may be appropriate, shall also be notified of the event or incident by the agency.

(k) During the second quarter of each year, the Department shall provide the Board an aggregate report summarizing by type the number of unusual events and incidents reported by agencies to the Department for the preceding calendar year.

(l) The Department shall work with representatives of agencies subject to these rules, and other interested parties, to develop recommendations to improve the collection and assimilation of specific aggregate health care data that, if known, would track health care trends over time and identify system-wide problems for broader quality improvement. The goal of such recommendations should be to better coordinate the collection of such data, to analyze the data, to identify potential problems and to work

(Rule 1200-08-34-.11, continued)

~~(e) The department shall approve in writing, the corrective action report if the department is satisfied that the corrective action plan appropriately addresses errors that contributed to the unusual event and takes the necessary steps to prevent the recurrence of the errors. If the department fails to approve the corrective action report, then the department shall provide the agency with a list of actions that the department believes are necessary to address the errors. The agency shall be offered an informal meeting with the Commissioner or the Commissioner's representative to attempt to resolve any disagreement over the corrective action report. If the department and the agency fail to agree on an appropriate corrective action plan, then the final determination on the adequacy of the corrective action report shall be made by the Board after a contested case hearing.~~

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~~(j) The affected consumer and/or the consumer's family, as may be appropriate, shall also be notified of the event or incident by the agency.~~

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~~(l) The Department shall work with representatives of agencies subject to these rules, and other interested parties, to develop recommendations to improve the collection and assimilation of specific aggregate health care data that, if known, would track health care trends over time and identify system-wide problems for broader quality improvement. The goal of such recommendations should be to better coordinate the collection of such data, to analyze the data, to identify potential problems and to work~~

(Rule 1200-08-34-.11, continued)

~~with agencies to develop best practices to remedy identified problems. The Department shall prepare and issue a report regarding such recommendations.~~

(2) The agency providing professional support services shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

(3) The agency providing professional support services shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the home care organization providing professional support services or to the health and safety of its patients and personnel; and

(d) Fires at the home care organization providing professional support services that disrupt the provision of patient care services or cause harm to the patients or staff, or that are reported by the facility to any entity, including but not limited to a fire department charged with preventing fires.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-207, 68-11-209, 68-11-210, and 68-11-211.* ***Administrative History:*** *Original rule filed January 24, 2003; effective April 9, 2003.*

1200-08-34-.12 CONSUMER RIGHTS.

(1) Each consumer has at least the following rights:

(a) To privacy in treatment and personal care;

(b) To have appropriate assessment and management of pain;

(c) To be involved in the decision making and all aspects of their care;

(d) To be free from mental and physical abuse. Should this right be violated, the agency must notify the Department within five (5) business days and the Tennessee Department of Human Services, Adult Protective Services as required by T.C.A. §71-6-101 et seq.;

(e) To refuse treatment. The consumer must be informed of the consequences of that decision, and the refusal and its reason must be reported to the physician and documented in the medical record;

(f) To refuse experimental treatment and drugs. The consumer's or health care decision maker's written consent for participation in research must be obtained and retained in the medical record; and

(g) To have their records kept confidential and private. Written consent by the consumer must be obtained prior to release of information except to persons authorized by law. If the consumer lacks capacity, written consent is required from the consumer's health

(Rule 1200-08-34-.12, continued)

care decision maker. The agency must have policies to govern access and duplication of the consumer's record.

(2) Each consumer has a right to self-determination, which encompasses the right to make choices regarding life-sustaining treatment, including resuscitative services. This right of self-determination may be effectuated by an advance directive.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, and 68-11-209.* ***Administrative History:*** *Original rule filed January 24, 2003; effective April 9, 2003. Amendment filed December 2, 2005; effective February 15, 2006.*

1200-08-34-.13 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING.

(1) Pursuant to this Rule, each professional support services agency shall maintain and establish policies and procedures governing the designation of a health care decision-maker for making health care decisions for a consumer who is incompetent or who lacks capacity, including but not limited to allowing the withholding of CPR measures from individual consumers. An adult or emancipated minor may give an individual instruction. The instruction may be oral or written. The instruction may be limited to take effect only if a specified condition arises.

(2) An adult or emancipated minor may execute an advance directive for health care. The advance directive may authorize an agent to make any health care decision the consumer could have made while having capacity, or may limit the power of the agent, and may include individual instructions. The effect of an advance directive that makes no limitation on the agent's authority shall be to authorize the agent to make any health care decision the consumer could have made while having capacity.

(3) The advance directive shall be in writing, signed by the consumer, and shall either be notarized or witnessed by two (2) witnesses. Both witnesses shall be competent adults, and neither of them may be the agent. At least one (1) of the witnesses shall be a person who is not related to the consumer by blood, marriage, or adoption and would not be entitled to any portion of the estate of the consumer upon the death of the consumer. The advance directive shall contain a clause that attests that the witnesses comply with the requirements of this paragraph.

(4) Unless otherwise specified in an advance directive, the authority of an agent becomes effective only upon a determination that the consumer lacks capacity, and ceases to be effective upon a determination that the consumer has recovered capacity.

~~(5) A facility shall use the mandatory advance directive form that meets the requirements of the Tennessee Health Care Decisions Act and has been developed and issued by the Board for Licensing Health Care Facilities.~~

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

(6) A determination that a consumer lacks or has recovered capacity, or that another condition exists that affects an individual instruction or the authority of an agent shall be made by the designated physician, who is authorized to consult with such other persons as he or she may deem appropriate.

(7) An agent shall make a health care decision in accordance with the consumer's individual instructions, if any, and other wishes to the extent known to the agent. Otherwise, the agent shall make the decision in accordance with the consumer's best interest. In determining the

(Rule 1200-08-34-.13, continued)

consumer's best interest, the agent shall consider the consumer's personal values to the extent known.

(8) An advance directive may include the individual's nomination of a court-appointed guardian.

(9) A health care facility shall honor an advance directive that is executed outside of this state by a nonresident of this state at the time of execution if that advance directive is in compliance with the laws of Tennessee or the state of the consumer's residence.

(10) No health care provider or institution shall require the execution or revocation of an advance directive as a condition for being insured for, or receiving, health care.

(11) Any living will, durable power of attorney for health care, or other instrument signed by the individual, complying with the terms of Tennessee Code Annotated, Title 32, Chapter 11, and a durable power of attorney for health care complying with the terms of Tennessee Code Annotated, Title 34, Chapter 6, Part 2, shall be given effect and interpreted in accord with those respective acts. Any advance directive that does not evidence an intent to be given effect under those acts but that complies with these regulations may be treated as an advance directive under these regulations.

(12) A consumer having capacity may revoke the designation of an agent only by a signed writing or by personally informing the supervising health care provider.

(13) A consumer having capacity may revoke all or part of an advance directive, other than the designation of an agent, at any time and in any manner that communicates an intent to revoke.

(14) A decree of annulment, divorce, dissolution of marriage, or legal separation revokes a previous designation of a spouse as an agent unless otherwise specified in the decree or in an advance directive.

(15) An advance directive that conflicts with an earlier advance directive revokes the earlier directive to the extent of the conflict.

(16) Surrogates.

(a) An adult or emancipated minor may designate any individual to act as surrogate by personally informing the supervising health care provider. The designation may be oral or written.

(b) A surrogate may make a health care decision for a consumer who is an adult or emancipated minor if and only if:

1. the consumer has been determined by the designated physician to lack capacity, and

2. no agent or guardian has been appointed, or

3. the agent or guardian is not reasonably available.

(c) In the case of a consumer who lacks capacity, the consumer's surrogate shall be identified by the supervising health care provider and documented in the current clinical record of the facility at which the consumer is receiving health care.

(Rule 1200-08-34-.13, continued)

(d) The consumer's surrogate shall be an adult who has exhibited special care and concern for the consumer, who is familiar with the consumer's personal values, who is reasonably available, and who is willing to serve.

(e) Consideration may be, but need not be, given in order of descending preference for service as a surrogate to:

1. the consumer's spouse, unless legally separated;

2. the consumer's adult child;

3. the consumer's parent;

4. the consumer's adult sibling;

5. any other adult relative of the consumer; or

6. any other adult who satisfies the requirements of 1200-08-34-.13(16)(d).

(f) No person who is the subject of a protective order or other court order that directs that person to avoid contact with the consumer shall be eligible to serve as the consumer's surrogate.

(g) The following criteria shall be considered in the determination of the person best qualified to serve as the surrogate:

1. Whether the proposed surrogate reasonably appears to be better able to make decisions either in accordance with the known wishes of the consumer or in accordance with the consumer's best interests;

2. The proposed surrogate's regular contact with the consumer prior to and during the incapacitating illness;

3. The proposed surrogate's demonstrated care and concern;

4. The proposed surrogate's availability to visit the consumer during his or her illness; and

5. The proposed surrogate's availability to engage in face-to-face contact with health care providers for the purpose of fully participating in the decision-making process.

(h) If the consumer lacks capacity and none of the individuals eligible to act as a surrogate under 1200-08-34-.13(16)(c) thru 1200-08-34-.13(16)(g) is reasonably available, the designated physician may make health care decisions for the consumer after the designated physician either:

1. Consults with and obtains the recommendations of a facility's ethics mechanism or standing committee in the facility that evaluates health care issues; or

2. Obtains concurrence from a second physician who is not directly involved in the consumer's health care, does not serve in a capacity of decision-making, influence, or responsibility over the designated physician, and is not under the designated physician's decision-making, influence, or responsibility.

(Rule 1200-08-34-.13, continued)

(i) In the event of a challenge, there shall be a rebuttable presumption that the selection of the surrogate was valid. Any person who challenges the selection shall have the burden of proving the invalidity of that selection.

(j) A surrogate shall make a health care decision in accordance with the consumer's individual instructions, if any, and other wishes to the extent known to the surrogate. Otherwise, the surrogate shall make the decision in accordance with the surrogate's determination of the consumer's best interest. In determining the consumer's best interest, the surrogate shall consider the consumer's personal values to the extent known to the surrogate.

(k) A surrogate who has not been designated by the consumer may make all health care decisions for the consumer that the consumer could make on the consumer's own behalf, except that artificial nutrition and hydration may be withheld or withdrawn for a consumer upon a decision of the surrogate only when the designated physician and a second independent physician certify in the consumer's current clinical records that the provision or continuation of artificial nutrition or hydration is merely prolonging the act of dying and the consumer is highly unlikely to regain capacity to make medical decisions.

(l) Except as provided in 1200-08-34-.13(16)(m):

1. Neither the treating health care provider nor an employee of the treating health care provider, nor an operator of a health care institution nor an employee of an operator of a health care institution may be designated as a surrogate; and

2. A health care provider or employee of a health care provider may not act as a surrogate if the health care provider becomes the consumer's treating health care provider.

(m) An employee of the treating health care provider or an employee of an operator of a health care institution may be designated as a surrogate if:

1. the employee so designated is a relative of the consumer by blood, marriage, or adoption; and

2. the other requirements of this section are satisfied.

(n) A health care provider may require an individual claiming the right to act as surrogate for a consumer to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(17) Guardian.

(a) A guardian shall comply with the consumer's individual instructions and may not revoke the consumer's advance directive absent a court order to the contrary.

(b) Absent a court order to the contrary, a health care decision of an agent takes precedence over that of a guardian.

(c) A health care provider may require an individual claiming the right to act as guardian for a consumer to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(18) A designated physician who makes or is informed of a determination that a consumer lacks or has recovered capacity, or that another condition exists which affects an individual instruction or the authority of an agent, guardian, or surrogate, shall promptly record the determination in

(Rule 1200-08-34-.13, continued)

the consumer's current clinical record and communicate the determination to the consumer, if possible, and to any person then authorized to make health care decisions for the consumer.

(19) Except as provided in 1200-08-34-.13(20) thru 1200-08-34-.13(22), a health care provider or institution providing care to a consumer shall:

(a) comply with an individual instruction of the consumer and with a reasonable interpretation of that instruction made by a person then authorized to make health care decisions for the consumer; and

(b) comply with a health care decision for the consumer made by a person then authorized to make health care decisions for the consumer to the same extent as if the decision had been made by the consumer while having capacity.

(20) A health care provider may decline to comply with an individual instruction or health care decision for reasons of conscience.

(21) A health care institution may decline to comply with an individual instruction or health care decision if the instruction or decision is:

(a) contrary to a policy of the institution which is based on reasons of conscience, and

(b) the policy was timely communicated to the consumer or to a person then authorized to make health care decisions for the consumer.

(22) A health care provider or institution may decline to comply with an individual instruction or health care decision that requires medically inappropriate health care or health care contrary to generally accepted health care standards applicable to the health care provider or institution.

(23) A health care provider or institution that declines to comply with an individual instruction or health care decision pursuant to 1200-08-34-.13(20) thru 1200-08-34-.13(22) shall:

(a) promptly so inform the consumer, if possible, and any person then authorized to make health care decisions for the consumer;

(b) provide continuing care to the consumer until a transfer can be effected or until the determination has been made that transfer cannot be effected;

(c) unless the consumer or person then authorized to make health care decisions for the consumer refuses assistance, immediately make all reasonable efforts to assist in the transfer of the consumer to another health care provider or institution that is willing to comply with the instruction or decision; and

(d) if a transfer cannot be effected, the health care provider or institution shall not be compelled to comply.

(24) Unless otherwise specified in an advance directive, a person then authorized to make health care decisions for a consumer has the same rights as the consumer to request, receive, examine, copy, and consent to the disclosure of medical or any other health care information.

(25) A health care provider or institution acting in good faith and in accordance with generally accepted health care standards applicable to the health care provider or institution is not subject to civil or criminal liability or to discipline for unprofessional conduct for:

(Rule 1200-08-34-.13, continued)

(a) complying with a health care decision of a person apparently having authority to make a health care decision for a consumer, including a decision to withhold or withdraw health care;

(b) declining to comply with a health care decision of a person based on a belief that the person then lacked authority; or

(c) complying with an advance directive and assuming that the directive was valid when made and had not been revoked or terminated.

(26) An individual acting as an agent or surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for health care decisions made in good faith.

(27) A person identifying a surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for such identification made in good faith.

(28) A copy of a written advance directive, revocation of an advance directive, or designation or disqualification of a surrogate has the same effect as the original.

(29) The withholding or withdrawal of medical care from a consumer in accordance with the provisions of the Tennessee Health Care Decisions Act shall not, for any purpose, constitute a suicide, euthanasia, homicide, mercy killing, or assisted suicide.

(30) Universal Do Not Resuscitate Order (DNR).

~~(a) The Physicians Order for Scope of Treatment (POST) form, a mandatory form meeting the provisions of the Health Care Decision Act and approved by the Board for Licensing Health Care Facilities, shall be used as the Universal Do Not Resuscitate Order by all facilities. A universal do not resuscitate order (DNR) may be used by a physician for his/her patient with whom he/she has a physician/patient relationship, but only:~~

~~1. with the consent of the patient; or~~

~~2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or~~

~~3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.~~

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do Not Resuscitate order may be used by a physician for a patient with whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of

(Rule 1200-08-34-.13, continued)

the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

(b) If the consumer is an adult who is capable of making an informed decision, the consumer's expression of the desire to be resuscitated in the event of cardiac or respiratory arrest shall revoke a universal do not resuscitate order. If the consumer is a minor or is otherwise incapable of making an informed decision, the expression of the desire that the consumer be resuscitated by the person authorized to consent on the consumer's behalf shall revoke a universal do not resuscitate order.

(c) Universal do not resuscitate orders shall remain valid and in effect until revoked. Qualified emergency medical services personnel, and licensed health care practitioners in any facility, program or organization operated or licensed by the board for licensing health care facilities or by the department of mental health and developmental disabilities or operated, licensed, or owned by another state agency are authorized to follow universal do not resuscitate orders.

(d) Nothing in these rules shall authorize the withholding of other medical interventions, such as intravenous fluids, oxygen, or other therapies deemed necessary to provide comfort care or to alleviate pain.

~~(e) If a person with a universal do not resuscitate order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the universal do not resuscitate order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the universal do not resuscitate order accompanies the consumer in transport to the receiving health care facility. Upon admission, the receiving facility shall make the universal do not resuscitate order a part of the consumer's record.~~

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

(f) This section shall not prevent, prohibit, or limit a physician from issuing a written order, other than a universal do not resuscitate order, not to resuscitate a consumer in the event of cardiac or respiratory arrest in accordance with accepted medical practices.

(g) Valid do not resuscitate orders or emergency medical services do not resuscitate orders issued before July 1, 2004, pursuant to the then-current law, shall remain valid and shall be given effect as provided.

(Rule 1200-08-34-.13, continued)
Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-224, 68-11-1801 through 68-11-1815.* ***Administrative History:*** *Original rule filed December 2, 2005; effective February 15, 2006. Amendment filed February 7, 2007; effective April 23, 2007.*

1200-08-34-.14 RESERVED.

RULES
OF
DEPARTMENT OF HEALTH
BOARD FOR LICENSING HEALTH CARE FACILITIES

CHAPTER 1200-08-35
STANDARDS FOR OUTPATIENT DIAGNOSTIC CENTERS

TABLE OF CONTENTS

1200-08-35-.01 DEFINITIONS.

(1) Acceptable Plan of Correction. The Licensing Division approves an Outpatient Diagnostic Center's plan to correct deficiencies identified during an on-site survey conducted by the Survey Division or its designated representative. The plan of correction shall be a written document and shall provide, but not limited to, the following information:

(a) How the deficiency will be corrected.

(b) Who will be responsible for correcting the deficiency.

(c) The date the deficiency will be corrected.

(d) How the facility will prevent the same deficiency from re-occurring.

(2) Accredited Record Technician (ART). A person currently accredited as such by the American Medical Records Association.

(3) Adult. An individual who has capacity and is at least 18 years of age.

(4) Agent. An individual designated in an advance directive for health care to make a health care decision for the individual granting the power.

(5) Advance Directive. An individual instruction or a written statement relating to the subsequent provision of health care for the individual, including, but not limited to, a living will or a durable power of attorney for health care.

(6) Board. The Tennessee Board for Licensing Health Care Facilities.

(7) Cancer Treatment and Radiation Clinic. A facility in which the only procedures performed are diagnostic and therapeutic radiology, chemotherapy and related services.

(8) Capacity. An individual's ability to understand the significant benefits, risks, and alternatives to proposed health care and to make and communicate a health care decision. These regulations do not affect the right of a patient to make health care decisions while having the capacity to do so. A patient shall be presumed to have capacity to make a health care decision, to give or revoke an advance directive, and to designate or disqualify a surrogate.

(Rule 1200-08-35-.01, continued)

Any person who challenges the capacity of a patient shall have the burden of proving lack of capacity.

(9) Cardiac Catheterization. An invasive procedure in which a transluminal catheter is inserted into the femoral, internal jugular or antecubital vein and guided through the venous system into the heart chambers and/or coronary arteries while the patient is under conscious sedation in order to provide anatomic information on the heart chambers, coronary arteries, valves, myocardium, and the great vessels.

(10) Cardiopulmonary Resuscitation (CPR). The administering of any means or device to support cardiopulmonary functions in a patient, whether by mechanical devices, chest compressions, mouth–to–mouth resuscitation, cardiac massage, tracheal intubation, manual or mechanical ventilators or respirators, defibrillation, the administration of drugs and/or chemical agents intended to restore cardiac and/or respiratory functions in a patient where cardiac or respiratory arrest has occurred or is believed to be imminent.

(11) Certified Registered Nurse Anesthetist. A registered nurse currently licensed by the Tennessee Board of Nursing who is currently certified as such by the American Association of Nurse Anesthetists.

(12) Collaborative Plan. The formal written plan between the mid-level practitioners and licensed physician.

(13) Collaborative Practice. The implementation of the collaborative plan that outlines procedures for consultation and collaboration with other health care professionals, e.g., licensed physicians, mid-level practitioners or nurse midwives.

(14) Commissioner. Commissioner of the Tennessee Department of Health or his or her authorized representative.

(15) Competent. A patient who has capacity.

(16) Computerized Tomography. A non-invasive radiological diagnostic procedure that may or may not include nuclear medical dye.

(17) Conscious Sedation. A drug induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are usually required to maintain a patient airway, and spontaneous ventilation is usually adequate. Cardiovascular function is usually maintained.

~~(18) Corrective Action Plan/Report. A report filed with the department by the facility after reporting an unusual event. The report must consist of the following:~~

~~(a) the action(s) implemented to prevent the reoccurrence of the unusual incident,~~

~~(b) the time frames for the action(s) to be implemented,~~

~~(c) the person(s) designated to implement and monitor the action(s), and~~

~~(d) the strategies for the measurements of effectiveness to be established.~~

(~~19~~18) Dentist. A person currently licensed as such by the Tennessee Board of Dentistry.

(~~20~~19) Department. The Tennessee Department of Health.

(Rule 1200-08-35-.01, continued)

(~~21~~20) Designated Physician. A physician designated by an individual or the individual's agent, guardian, or surrogate, to have primary responsibility for the individual's health care or, in the absence of a designation or if the designated physician is not reasonably available, a physician who undertakes such responsibility.

(~~22~~21) Do Not Resuscitate (DNR) Order. An order entered by the patient's treating physician in the patient's medical records which states that in the event the patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The order may contain limiting language to allow only certain types of cardiopulmonary resuscitation.

(~~23~~22) Electronic Signature. The authentication of a health record document or documentation in an electronic form achieved through electronic entry of an exclusively assigned, unique identification code entered by the author of the documentation.

(~~24~~23) Emancipated Minor. Any minor who is or has been married or has by court order or otherwise been freed from the care, custody and control of the minor's parents.

(~~25~~24) Emergency Responder. A paid or volunteer firefighter, law enforcement officer, or other public safety official or volunteer acting within the scope of his or her proper function under law or rendering emergency care at the scene of an emergency.

(~~26~~25) Graduate Registered Nurse Anesthetist. A registered nurse currently licensed in Tennessee who is a graduate of a nurse anesthesia educational program that is accredited by the American Association of Nurse Anesthetist's Council on Accreditation of Nurse Anesthesia Educational Programs and awaiting initial certification examination results, provided that initial certification is accomplished within eighteen (18) months of completion of an accredited nurse anesthesia educational program.

(~~27~~26) Guardian. A judicially appointed guardian or conservator having authority to make a health care decision for an individual.

(~~28~~27) Hazardous Waste. Materials whose handling, use, storage and disposal are governed by local, state or federal regulations.

(~~29~~28) Health Care. Any care, treatment, service or procedure to maintain, diagnose, treat, or otherwise affect an individual's physical or mental condition, and includes medical care as defined in T.C.A. § 32-11-103(5).

(~~30~~29) Health Care Decision. Consent, refusal of consent or withdrawal of consent to health care.

(~~31~~30) Health Care Decision-maker. In the case of a patient who lacks capacity, the patient's health care decision-maker is one of the following: the patient's health care agent as specified in an advance directive, the patient's court-appointed guardian or conservator with health care decision-making authority, the patient's surrogate as determined pursuant to Rule 1200-08-35-.13 or T.C.A. §33-3-220, the designated physician pursuant to these Rules or in the case of a minor child, the person having custody or legal guardianship.

(~~32~~31) Health Care Institution. A health care institution as defined in T.C.A. § 68-11-1602.

(~~33~~32) Health Care Provider. A person who is licensed, certified or otherwise authorized or permitted by the laws of this state to administer health care in the ordinary course of business or practice of a profession.

(~~34~~33) Incompetent. A patient who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.

(Rule 1200-08-35-.01, continued)

(~~35~~34) Individual instruction. An individual's direction concerning a health care decision for the individual.

(~~36~~35) Infectious Waste. Solid or liquid wastes which contain pathogens with sufficient virulence and quantity such that exposure to the waste by a susceptible host could result in an infectious disease.

(~~37~~36) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(~~38~~37) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all applicable rules and regulations.

(~~39~~38) Life Threatening or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

(~~40~~39) Lithotripsy. A technique using extracorporeal shock waves to break up stones that form in the kidney, bladder, ureters, or gallbladder while monitoring through x-ray or ultrasound.

(~~41~~40) Magnetic Resonance Imaging (MRI). A non-invasive diagnostic technique that produces computerized images of internal body tissues and is based on nuclear magnetic resonance of atoms within the body induced by the application of radio waves.

(~~42~~41) Mammography. A non-invasive radiological procedure used to take pictures of the breasts in order to diagnose tumors or cysts.

(~~43~~42) Medical Emergency. A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the patient's health in serious jeopardy, serious impairment to bodily functions or serious dysfunction of any bodily organ or part.

(~~44~~43) Medical Record. Medical histories, records, reports, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries, x-rays, radiology interpretations and other written electronics, or graphic data prepared, kept, made or maintained in a facility that pertains to confinement or services rendered to patients admitted or receiving care.

(~~45~~44) Medical Staff. An organized body composed of individuals appointed by the Outpatient Diagnostic Center governing board. All members of the medical staff shall be licensed to practice in Tennessee, with the exception of interns and residents.

(~~46~~45) Medically Inappropriate Treatment. Resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the patient or other medical or surgical treatments to achieve the expressed goals of the informed patient. In the case of the incompetent patient, the patient's representative expresses the goals of the patient.

(~~47~~46) Mid-Level Practitioner. A registered nurse licensed in Tennessee who holds a master's degree in a clinical nursing specialty, national certification through the ANCC or American Academy of Nurse Practitioners and holds a certificate of fitness to prescribe from the Tennessee Board of Nursing.

(~~48~~47) N.F.P.A. National Fire Protection Association.

(Rule 1200-08-35-.01, continued)

(~~49~~48) Nurse Midwife. A person currently licensed by the Tennessee Board of Nursing as a registered nurse (R.N.) and qualified to deliver midwifery services or certified by the American College of Nurse-Midwives.

(~~50~~49) Outpatient Diagnostic Center. Any facility providing outpatient diagnostic services (computerized tomography, magnetic resonance imaging, positron emission tomography, or other imaging technology developed after June 9, 2005 which provides substantially the same functionality), unless the outpatient diagnostic services are provided as the services of another licensed healthcare institution that reports such outpatient diagnostic services on its joint annual report, or the facility is otherwise excluded from this definition. Outpatient diagnostic center does not include a physician or dental practice that is conducted at a location occupied and controlled by one or more physicians or dentists licensed under Title 63, if the outpatient diagnostic services are ancillary to the specialties of the physicians' practice or are provided primarily for persons who are patients of the physicians or dentists in the practice for purposes other than outpatient diagnostic services. Outpatient diagnostic centers in existence prior to the effective date of this rule will be required to obtain licensure by the department of health and comply with relevant reporting requirements.

(~~51~~50) Patient. Includes but is not limited to any person who is suffering from an acute or chronic illness or injury or who is crippled, convalescent or infirm, or who is in need of obstetrical, surgical, medical, nursing or supervisory care.

(~~52~~51) Patient Abuse. atient neglect, intentional infliction of pain, injury, or mental anguish. Patient abuse includes the deprivation of services by a caretaker which are necessary to maintain the health and welfare of a patient or resident; however, the withholding of authorization for or provision of medical care to any terminally ill person who has executed an irrevocable living will in accordance with the Tennessee Right to Natural Death Law, or other applicable state law, if the provision of such medical care would conflict with the terms of such living will shall not be deemed "patient abuse" for purposes of these rules.

(~~53~~52) Percutaneous Transluminal Coronary Angioplasty. An invasive diagnostic procedure in which a transluminal catheter is guided through the femoral, subclavian, internal jugular or antecubital vein allowing the passage of a balloon-tipped catheter distally into the coronary artery while viewing through radiological pictures. The balloon is aligned within the stenosis and inflated to dilate the vessel with or without the use of anticoagulants to reduce the incidence of thrombosis at the site of balloon dilation and calcium blockers or nitrates to reduce coronary spasm. Conscious sedation and local anesthesia at catheter insertion site are utilized during the procedure.

(~~54~~53) Person. An individual, corporation, estate, trust, partnership, association, joint venture, government, governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.

(~~55~~54) Personally Informing. A communication by any effective means from the patient directly to a health care provider.

(~~56~~55) Physician. An individual authorized to practice medicine or osteopathy under Tennessee Code Annotated, Title 63, Chapters 6 or 9.

(~~57~~56) Physician Assistant. A person who is licensed by the Tennessee Board of Medical Examiners and Committee on Physician Assistants and has obtained prescription writing authority pursuant to T.C.A. §63-19-107(2)(A).

(~~58~~57) Positron Emission Tomography (PET Scan). A non-invasive radiological procedure producing a sectional view of the body constructed by positron-emission tomography.

(Rule 1200-08-35-.01, continued)

(~~59~~58) Power of Attorney for Health Care. The designation of an agent to make health care decisions for the individual granting the power under T.C.A. Title 34, Chapter 6, Part 2.

(~~60~~59) Qualified Emergency Medical Service Personnel. Includes, but shall not be limited to, emergency medical technicians, paramedics, or other emergency services personnel, providers, or entities acting within the usual course of their professions, and other emergency responders.

(~~61~~60) Radiological Technologist. A person currently certified as such by the American Society of Radiological Technologists.

(~~62~~61) Reasonably Available. Readily able to be contacted without undue effort and willing and able to act in a timely manner considering the urgency of the patient's health care needs. Such availability shall include, but not be limited to, availability by telephone.

(~~63~~62) Registered Nurse (R.N.). A person currently licensed as such by the Tennessee Board of Nursing.

(~~64~~63) Registered Record Administrator (RRA). A person currently registered as such by the American Medical Records Association.

(~~65~~64) Shall or Must. Compliance is mandatory.

(~~66~~65) State. A state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.

(~~67~~66) Stereotactic Procedure. An invasive technique utilized for precisely directing the tip of a delicate needle or beam of radiation in three planes using coordinates provided by medical imaging such as x-ray or CT scan in order to reach a specific location in the body, eg. tumor.

(~~68~~67) Supervising Health Care Provider. The designated physician or, if there is no designated physician or the designated physician is not reasonably available, the health care provider who has undertaken primary responsibility for an individual's health care.

(~~69~~68) Surrogate. An individual, other than a patient's agent or guardian, authorized to make a health care decision for the patient.

(~~70~~69) Transfer. The movement of a patient at the direction of a physician or other qualified medical personnel when a physician is not readily available but does not include such movement of a patient who leaves the facility against medical advice.

(~~71~~70) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the patient.

(71) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

~~(72) Universal Do Not Resuscitate Order. A written order that applies regardless of the treatment setting and that is signed by the patient's physician which states that in the event the patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The Physician Order for Scope of Treatment (POST) form promulgated by the Board for Licensing Health Care Facilities shall serve as a Universal DNR according to these rules.~~

(Rule 1200-08-35-.10, continued)

disinfection of materials included in the cycle, and records kept. Proper operation of such devices must be verified at least monthly, and records of these monthly checks shall be available for review. Waste that contains toxic chemicals that would be volatilized by steam must not be treated in steam sterilizers. Infectious waste that has been rendered to a carbonized or mineralized ash shall be deemed non-infectious. Unless otherwise hazardous and subject to the hazardous waste management requirements of the current rules of the Department of Environment and Conservation, such ash shall be disposable as a (non-hazardous) solid waste under current rules of the Department of Environment and Conservation.

(b) The facility may discharge liquid or semi-liquid infectious waste to the collection sewerage system of a wastewater treatment facility which is subject to a permit pursuant to T.C.A. § 69-3-101 et seq., provided that such discharge is in accordance with any applicable terms of that permit and/or any applicable municipal sewer use requirements.

(c) Any health care facility accepting waste from another state must promptly notify the Department of Environment and Conservation, county and city public health agencies, and must strictly comply with all applicable local, state and federal regulations.

(9) The facility may have waste transported off-site for storage, treatment, or disposal. Such arrangements must be detailed in a written contract, available for review. If such off-site location is located within Tennessee, the facility must ensure that it has all necessary State and local approvals, and such approvals shall be available for review. If the off-site location is within another state, the facility must notify in writing all public health agencies with jurisdiction that the location is being used for management of the facility's waste. Waste shipped off-site must be packaged in accordance with applicable Federal and State requirements. Waste transported to a sanitary landfill in this state must meet the requirements of current rules of the Department of Environment and Conservation.

(10) Human anatomical remains which are transferred to a mortician for cremation or burial shall be exempt from the requirements of this subparagraph. Any other human limbs and recognizable organs must be incinerated or discharged (following grinding) to the sewer.

(11) All garbage, trash and other non-infectious wastes shall be stored and disposed of in a manner that must not permit the transmission of disease, create a nuisance, provide a breeding place for insects and rodents, or constitute a safety hazard. All containers for waste shall be water tight, be constructed of easily cleanable material and be kept on elevated platforms.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed October 26, 2005; effective January 9, 2006.*

1200-08-35-.11 RECORDS AND REPORTS.

(1) The Joint Annual Report of Outpatient Diagnostic Centers shall be filed with the department. The forms are furnished and mailed to each Outpatient Diagnostic Center by the department each year and the forms must be completed and returned to the department as required.

(2) The facility shall report information contained in the medical records of patients who have cancer or pre-cancerous or tumorous diseases as provided by existing regulations. These reports shall be sent to the Cancer Reporting System of the department on a quarterly schedule no later than six (6) months after the date of the diagnosis or treatment.

(Rule 1200-08-35-.11, continued)

(3) The Outpatient Diagnostic Center shall report to the department each case of communicable disease detected in the center. Repeated failure to report communicable diseases shall be cause for revocation of an Outpatient Diagnostic Center's license.

~~(4) Unusual events shall be reported by the facility to the Department of Health in a format designed by the Department within seven (7) business days of the date of the identification of the abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient.~~

~~(a) The following represent circumstances that could result in an unusual event that is an unexpected occurrence or accident resulting in death, life threatening or serious injury to a patient, not related to a natural course of the patient's illness or underlying condition. The circumstances that could result in an unusual event include, but are not limited to:~~

~~1. medication errors;~~

~~2. aspiration in a non-intubated patient related to conscious/moderate sedation;~~

~~3. intravascular catheter related events including necrosis or infection requiring repair or intravascular catheter related pneumothorax;~~

~~4. volume overload leading to pulmonary edema;~~

~~5. blood transfusion reactions, use of wrong type of blood and/or delivery of blood to the wrong patient;~~

~~6. perioperative/periprocedural related complication(s) that occur within 48 hours of the operation or the procedure, including a procedure which results in any new central neurological deficit or any new peripheral neurological deficit with motor weakness;~~

~~7. burns of a second or third degree;~~

~~8. falls resulting in radiologically proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage, and/or internal trauma, but does not include fractures resulting from pathological conditions;~~

~~9. procedure related incidents, regardless of setting and within thirty (30) days of the procedure and includes readmissions, which include:~~

~~(i) procedure related injury requiring repair or removal of an organ;~~

~~(ii) hemorrhage;~~

~~(iii) displacement, migration or breakage of an implant, device, graft or drain;~~

~~(iv) post operative wound infection following clean or clean/contaminated case;~~

~~(v) any unexpected operation or reoperation related to the primary procedure;~~

~~(vi) hysterectomy in a pregnant woman;~~

~~(vii) ruptured uterus;~~

~~(viii) circumcision;~~

(Rule 1200-08-35-.11, continued)

(ix) incorrect procedure or incorrect treatment that is invasive;

(x) wrong patient/wrong site surgical procedure;

(xi) unintentionally retained foreign body;

(xii) loss of limb or organ, or impairment of limb if the impairment is present at discharge or for least two (2) weeks after occurrence;

(xiii) criminal acts;

(xiv) suicide or attempted suicide;

(xv) elopement from the facility;

(xvi) infant abduction, or infant discharged to the wrong family;

(xvii) adult abduction;

(xviii) rape;

(xix) patient altercation;

(xx) patient abuse, patient neglect, or misappropriation of resident/patient funds;

(xxi) restraint related incidents; or

(xxii) poisoning occurring within the facility.

(b) Specific incidents that might result in a disruption of the delivery of health care services at the facility shall also be reported to the department, on the unusual event form, within seven (7) days after the facility learns of the incident. These specific incidents include the following:

1. strike by the staff at the facility;

2. external disaster impacting the facility;

3. disruption of any service vital to the continued safe operation of the facility or to the health and safety of its patients and personnel; and

4. fires at the facility which disrupt the provision of patient care services or cause harm to patients or staff, or which are reported by the facility to any entity, including but not limited to a fire department, charged with preventing fires.

(c) For health services provided in a "home" setting, only those unusual events actually witnessed or known by the person delivering health care services are required to be reported.

(d) Within forty (40) days of the identification of the event, the facility shall file with the department a corrective action report for the unusual event reported to the department. The department's approval of a Corrective Action Report will take into consideration whether the facility utilized an analysis in identifying the most basic or causal factor(s) that underlie variation in performance leading to the unusual event by (a) determining

(Rule 1200-08-35-.11, continued)

the proximate cause of the unusual event, (b) analyzing the systems and processes involved in the unusual event, (c) identifying possible common causes, (d) identifying potential improvements, and (e) identifying measures of effectiveness. The corrective action report shall either: (1) explain why a corrective action report is not necessary; or (2) detail the actions taken to correct any error identified that contributed to the unusual event or incident, the date the corrections were implemented, how the facility will prevent the error from recurring in the future and who will monitor the implementation of the corrective action plan.

(e) The department shall approve in writing, the corrective action report if the department is satisfied that the corrective action plan appropriately addresses errors that contributed to the unusual event and takes the necessary steps to prevent the recurrence of the errors. If the department fails to approve the corrective action report, then the department shall provide the facility with a list of actions that the department believes are necessary to address the errors. The facility shall be offered an informal meeting with the Commissioner or the Commissioner's representative to attempt to resolve any disagreement over the corrective action report. If the department and the facility fail to agree on an appropriate corrective action plan, then the final determination on the adequacy of the corrective action report shall be made by the Board after a contested case hearing.

(f) The event report reviewed or obtained by the department shall be confidential and not subject to discovery, subpoena or legal compulsion for release to any person or entity, nor shall the report be admissible in any civil or administrative proceeding other than a disciplinary proceeding by the department or the appropriate regulatory board. The report is not discoverable or admissible in any civil or administrative action except that information in any such report may be transmitted to an appropriate regulatory agency having jurisdiction for disciplinary or license sanctions against the impacted facility. The department must reveal upon request its awareness that a specific event or incident has been reported.

(g) The department shall have access to facility records as allowed in Title 68, Chapter 11, Part 3. The department may copy any portion of a facility medical record relating to the reported event unless otherwise prohibited by rule or statute. This section does not change or affect the privilege and confidentiality provided by T.C.A. §63-6-219.

(h) The department, in developing the unusual event report form, shall establish an event occurrence code that categorizes events or specific incidents by the examples set forth above in (a) and (b). If an event or specific incident fails to come within these examples, it shall be classified as "other" with the facility explaining the facts related to the event or incident.

(i) This does not preclude the department from using information obtained under these rules in a disciplinary action commenced against a facility, or from taking a disciplinary action against a facility. Nor does this preclude the department from sharing such information with any appropriate governmental agency charged by federal or state law with regulatory oversight of the facility. However, all such information must at all times be maintained as confidential and not available to the public. Failure to report an unusual event, submit a corrective action report, or comply with a plan of correction as required herein may be grounds for disciplinary action pursuant to T.C.A. §68-11-207.

(j) The affected patient and/or the patient's family, as may be appropriate, shall also be notified of the event or incident by the facility.

(Rule 1200-08-35-.11, continued)

~~(k) During the second quarter of each year, the Department shall provide the Board an aggregate report summarizing by type the number of unusual events and incidents reported by facilities to the Department for the preceding calendar year.~~

~~(l) The Department shall work with representatives of facilities subject to these rules, and other interested parties, to develop recommendations to improve the collection and assimilation of specific aggregate health care data that, if known, would track health care trends over time and identify system-wide problems for broader quality improvement. The goal of such recommendations should be to better coordinate the collection of such data, to analyze the data, to identify potential problems and to work with facilities to develop best practices to remedy identified problems. The Department shall prepare and issue a report regarding such recommendations.~~

(4) The outpatient diagnostic center shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

(5) The outpatient diagnostic center shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the outpatient diagnostic center or to the health and safety of its patients and personnel; and

(d) Fires at the outpatient diagnostic center that disrupt the provision of patient care services or cause harm to the patients or staff, or that are reported by the facility to any entity, including but not limited to a fire department charged with preventing fires.

(~~5~~6) Legible copies of the following records and reports shall be retained in the Outpatient Diagnostic Center, shall be maintained in a single file, and shall be made available for inspection during normal business hours to any patient who requests to view them for thirty-six (36) months following their issuance:

(a) Local fire safety inspections;

(b) Local building code inspections, if any;

(c) Fire marshal reports;

(d) Department licensure and fire safety inspections and surveys;

(e) Department quality assurance surveys, including follow-up visits, and certification inspections, if any;

(f) Federal Center for Medicare and Medicaid Services surveys and inspections, if any;

(g) Orders of the Commissioner or Board, if any;

(h) Comptroller of the Treasury's audit reports and findings, if any;

(i) Maintenance records of all safety equipment; and

(j) Radiological inspection reports.

(Rule 1200-08-35-.11, continued)

(6) Copies of patient's medical records shall be maintained for at least ten (10) years.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-1-1004, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-211, and 68-11-216.* ***Administrative History:*** *Original rule filed October 26, 2005; effective January 9, 2006.*

1200-08-35-.12 PATIENT RIGHTS.

(1) Each patient has at least the following rights:

(a) To privacy in treatment and personal care;

(b) To be free from mental and physical abuse. Should this right be violated, the facility must notify the department within five (5) business days and the Tennessee Department of Human Services, Adult Protective Services immediately as required by T.C.A. § 71-6-101 et seq;

(c) To refuse treatment. The patient must be informed of the consequences of that decision, the refusal and its reason must be reported to the physician and documented in the medical record;

(d) To refuse experimental treatment and drugs. The patient's or health care decision maker's written consent for participation in research must be obtained and retained in his or her medical record;

(e) To have their records kept confidential and private. Written consent by the patient must be obtained prior to release of information except to persons authorized by law. If the patient lacks capacity, written consent is required from the patient's health care decision maker. The outpatient diagnostic center must have policies to govern access and duplication of the patient's record;

(f) To have appropriate assessment and management of pain; and

(g) To be involved in the decision making of all aspects of their care.

(2) Each patient has a right to self-determination, which encompasses the right to make choices regarding life-sustaining treatment (including resuscitative services). This right of self-determination may be effectuated by an advance directive.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed October 26, 2005; effective January 9, 2006.*

1200-08-35-.13 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING.

(1) Pursuant to this Rule, each outpatient diagnostic center shall maintain and establish policies and procedures governing the designation of a health care decision-maker for making health care decisions for a patient who is incompetent or who lacks capacity, including but not limited to allowing the withholding of CPR measures from individual patients. An adult or emancipated minor may give an individual instruction. The instruction may be oral or written. The instruction may be limited to take effect only if a specified condition arises.

(2) An adult or emancipated minor may execute an advance directive for health care. The advance directive may authorize an agent to make any health care decision the patient could have made while having capacity, or may limit the power of the agent, and may include individual instructions. The effect of an advance directive that makes no limitation on the

(Rule 1200-08-35-.13, continued)

agent's authority shall be to authorize the agent to make any health care decision the patient could have made while having capacity.

(3) The advance directive shall be in writing, signed by the patient, and shall either be notarized or witnessed by two (2) witnesses. Both witnesses shall be competent adults, and neither of them may be the agent. At least one (1) of the witnesses shall be a person who is not related to the patient by blood, marriage, or adoption and would not be entitled to any portion of the estate of the patient upon the death of the patient. The advance directive shall contain a clause that attests that the witnesses comply with the requirements of this paragraph.

(4) Unless otherwise specified in an advance directive, the authority of an agent becomes effective only upon a determination that the patient lacks capacity, and ceases to be effective upon a determination that the patient has recovered capacity.

~~(5) A facility may use any advance directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.~~

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

(6) A determination that a patient lacks or has recovered capacity, or that another condition exists that affects an individual instruction or the authority of an agent shall be made by the designated physician, who is authorized to consult with such other persons as he or she may deem appropriate.

(7) An agent shall make a health care decision in accordance with the patient's individual instructions, if any, and other wishes to the extent known to the agent. Otherwise, the agent shall make the decision in accordance with the patient's best interest. In determining the patient's best interest, the agent shall consider the patient's personal values to the extent known.

(8) An advance directive may include the individual's nomination of a court-appointed guardian.

(9) A health care facility shall honor an advance directive that is executed outside of this state by a nonresident of this state at the time of execution if that advance directive is in compliance with the laws of Tennessee or the state of the patient's residence.

(10) No health care provider or institution shall require the execution or revocation of an advance directive as a condition for being insured for, or receiving, health care.

(11) Any living will, durable power of attorney for health care, or other instrument signed by the individual, complying with the terms of Tennessee Code Annotated, Title 32, Chapter 11, and a durable power of attorney for health care complying with the terms of Tennessee Code Annotated, Title 34, Chapter 6, Part 2, shall be given effect and interpreted in accord with those respective acts. Any advance directive that does not evidence an intent to be given effect under those acts but that complies with these regulations may be treated as an advance directive under these regulations.

(12) A patient having capacity may revoke the designation of an agent only by a signed writing or by personally informing the supervising health care provider.

(13) A patient having capacity may revoke all or part of an advance directive, other than the designation of an agent, at any time and in any manner that communicates an intent to revoke.

(Rule 1200-08-35-.13, continued)

(14) A decree of annulment, divorce, dissolution of marriage, or legal separation revokes a previous designation of a spouse as an agent unless otherwise specified in the decree or in an advance directive.

(15) An advance directive that conflicts with an earlier advance directive revokes the earlier directive to the extent of the conflict.

(16) Surrogates.

(a) An adult or emancipated minor may designate any individual to act as surrogate by personally informing the supervising health care provider. The designation may be oral or written.

(b) A surrogate may make a health care decision for a patient who is an adult or emancipated minor if and only if:

1. the patient has been determined by the designated physician to lack capacity, and

2. no agent or guardian has been appointed, or

3. the agent or guardian is not reasonably available.

(c) In the case of a patient who lacks capacity, the patient's surrogate shall be identified by the supervising health care provider and documented in the current clinical record of the facility at which the patient is receiving health care.

(d) The patient's surrogate shall be an adult who has exhibited special care and concern for the patient, who is familiar with the patient's personal values, who is reasonably available, and who is willing to serve.

(e) Consideration may be, but need not be, given in order of descending preference for service as a surrogate to:

1. the patient's spouse, unless legally separated;

2. the patient's adult child;

3. the patient's parent;

4. the patient's adult sibling;

5. any other adult relative of the patient; or

6. any other adult who satisfies the requirements of 1200-08-35-.13(16)(d).

(f) No person who is the subject of a protective order or other court order that directs that person to avoid contact with the patient shall be eligible to serve as the patient's surrogate.

(g) The following criteria shall be considered in the determination of the person best qualified to serve as the surrogate:

(Rule 1200-08-35-.13, continued)

1. Whether the proposed surrogate reasonably appears to be better able to make decisions either in accordance with the known wishes of the patient or in accordance with the patient's best interests;

2. The proposed surrogate's regular contact with the patient prior to and during the incapacitating illness;

3. The proposed surrogate's demonstrated care and concern;

4. The proposed surrogate's availability to visit the patient during his or her illness; and

5. The proposed surrogate's availability to engage in face-to-face contact with health care providers for the purpose of fully participating in the decision-making process.

(h) If the patient lacks capacity and none of the individuals eligible to act as a surrogate under 1200-08-35-.13(16)(c) thru 1200-08-35-.13(16)(g) is reasonably available, the designated physician may make health care decisions for the patient after the designated physician either:

1. Consults with and obtains the recommendations of a facility's ethics mechanism or standing committee in the facility that evaluates health care issues; or

2. Obtains concurrence from a second physician who is not directly involved in the patient's health care, does not serve in a capacity of decision-making, influence, or responsibility over the designated physician, and is not under the designated physician's decision-making, influence, or responsibility.

(i) In the event of a challenge, there shall be a rebuttable presumption that the selection of the surrogate was valid. Any person who challenges the selection shall have the burden of proving the invalidity of that selection.

(j) A surrogate shall make a health care decision in accordance with the patient's individual instructions, if any, and other wishes to the extent known to the surrogate. Otherwise, the surrogate shall make the decision in accordance with the surrogate's determination of the patient's best interest. In determining the patient's best interest, the surrogate shall consider the patient's personal values to the extent known to the surrogate.

(k) A surrogate who has not been designated by the patient may make all health care decisions for the patient that the patient could make on the patient's own behalf, except that artificial nutrition and hydration may be withheld or withdrawn for a patient upon a decision of the surrogate only when the designated physician and a second independent physician certify in the patient's current clinical records that the provision or continuation of artificial nutrition or hydration is merely prolonging the act of dying and the patient is highly unlikely to regain capacity to make medical decisions.

(l) Except as provided in 1200-08-35-.13(16)(m):

1. Neither the treating health care provider nor an employee of the treating health care provider, nor an operator of a health care institution nor an employee of an operator of a health care institution may be designated as a surrogate; and

(Rule 1200-08-35-.13, continued)

2. A health care provider or employee of a health care provider may not act as a surrogate if the health care provider becomes the patient's treating health care provider.

(m) An employee of the treating health care provider or an employee of an operator of a health care institution may be designated as a surrogate if:

1. the employee so designated is a relative of the patient by blood, marriage, or adoption; and

2. the other requirements of this section are satisfied.

(n) A health care provider may require an individual claiming the right to act as surrogate for a patient to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(17) Guardian.

(a) A guardian shall comply with the patient's individual instructions and may not revoke the patient's advance directive absent a court order to the contrary.

(b) Absent a court order to the contrary, a health care decision of an agent takes precedence over that of a guardian.

(c) A health care provider may require an individual claiming the right to act as guardian for a patient to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(18) A designated physician who makes or is informed of a determination that a patient lacks or has recovered capacity, or that another condition exists which affects an individual instruction or the authority of an agent, guardian, or surrogate, shall promptly record the determination in the patient's current clinical record and communicate the determination to the patient, if possible, and to any person then authorized to make health care decisions for the patient.

(19) Except as provided in 1200-08-35-.13(20) thru 1200-08-35-.13(22), a health care provider or institution providing care to a patient shall:

(a) comply with an individual instruction of the patient and with a reasonable interpretation of that instruction made by a person then authorized to make health care decisions for the patient; and

(b) comply with a health care decision for the patient made by a person then authorized to make health care decisions for the patient to the same extent as if the decision had been made by the patient while having capacity.

(20) A health care provider may decline to comply with an individual instruction or health care decision for reasons of conscience.

(21) A health care institution may decline to comply with an individual instruction or health care decision if the instruction or decision is:

(a) contrary to a policy of the institution which is based on reasons of conscience, and

(b) the policy was timely communicated to the patient or to a person then authorized to make health care decisions for the patient.

(Rule 1200-08-35-.13, continued)

(22) A health care provider or institution may decline to comply with an individual instruction or health care decision that requires medically inappropriate health care or health care contrary to generally accepted health care standards applicable to the health care provider or institution.

(23) A health care provider or institution that declines to comply with an individual instruction or health care decision pursuant to 1200-08-35-.13(20) thru 1200-08-35-.13(22) shall:

(a) promptly so inform the patient, if possible, and any person then authorized to make health care decisions for the patient;

(b) provide continuing care to the patient until a transfer can be effected or until the determination has been made that transfer cannot be effected;

(c) unless the patient or person then authorized to make health care decisions for the patient refuses assistance, immediately make all reasonable efforts to assist in the transfer of the patient to another health care provider or institution that is willing to comply with the instruction or decision; and

(d) if a transfer cannot be effected, the health care provider or institution shall not be compelled to comply.

(24) Unless otherwise specified in an advance directive, a person then authorized to make health care decisions for a patient has the same rights as the patient to request, receive, examine, copy, and consent to the disclosure of medical or any other health care information.

(25) A health care provider or institution acting in good faith and in accordance with generally accepted health care standards applicable to the health care provider or institution is not subject to civil or criminal liability or to discipline for unprofessional conduct for:

(a) complying with a health care decision of a person apparently having authority to make a health care decision for a patient, including a decision to withhold or withdraw health care;

(b) declining to comply with a health care decision of a person based on a belief that the person then lacked authority; or

(c) complying with an advance directive and assuming that the directive was valid when made and had not been revoked or terminated.

(26) An individual acting as an agent or surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for health care decisions made in good faith.

(27) A person identifying a surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for such identification made in good faith.

(28) A copy of a written advance directive, revocation of an advance directive, or designation or disqualification of a surrogate has the same effect as the original.

(29) The withholding or withdrawal of medical care from a patient in accordance with the provisions of the Tennessee Health Care Decisions Act shall not, for any purpose, constitute a suicide, euthanasia, homicide, mercy killing, or assisted suicide.

(30) Universal Do Not Resuscitate Order (DNR).

(Rule 1200-08-35-.13, continued)

~~(a) A universal do not resuscitate order (DNR) may be issued by a physician for his/her patient with whom he/she has a physician/patient relationship, but only:~~

~~1. with the consent of the patient; or~~

~~2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or~~

~~3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.~~

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do Not Resuscitate Order may be used by a physician for a patient whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

(b) If the patient is an adult who is capable of making an informed decision, the patient's expression of the desire to be resuscitated in the event of cardiac or respiratory arrest shall revoke a universal do not resuscitate order. If the patient is a minor or is otherwise incapable of making an informed decision, the expression of the desire that the patient be resuscitated by the person authorized to consent on the patient's behalf shall revoke a universal do not resuscitate order.

(c) Universal do not resuscitate orders shall remain valid and in effect until revoked. Qualified emergency medical services personnel, and licensed health care practitioners in any facility, program or organization operated or licensed by the board for licensing health care facilities or by the department of mental health and developmental disabilities or operated, licensed, or owned by another state agency are authorized to follow universal do not resuscitate orders.

(d) Nothing in these rules shall authorize the withholding of other medical interventions, such as intravenous fluids, oxygen, or other therapies deemed necessary to provide comfort care or to alleviate pain.

(Rule 1200-08-35-.13, continued)

~~(e) If a person with a universal do not resuscitate order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the universal do not resuscitate order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the universal do not resuscitate order accompanies the patient in transport to the receiving health care facility. Upon admission, the receiving facility shall make the universal do not resuscitate order a part of the patient's record.~~

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

(f) This section shall not prevent, prohibit, or limit a physician from issuing a written order, other than a universal do not resuscitate order, not to resuscitate a patient in the event of cardiac or respiratory arrest in accordance with accepted medical practices.

(g) Valid do not resuscitate orders or emergency medical services do not resuscitate orders issued before July 1, 2004, pursuant to the then-current law, shall remain valid and shall be given effect as provided.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-224, 68-11-1803, 68-11-1804, 68-11-1806 through 68-11-1810, 68-11-1813, and 68-11-1814.* ***Administrative History****: Original rule filed October 26, 2005; effective January 9, 2006.*

1200-08-35-.14 DISASTER PREPAREDNESS.

(1) The administration of every facility shall have in effect and available for all supervisory personnel and staff, written copies of the following required disaster plans for the protection of all persons in the event of fire and other emergencies for evacuation to areas of refuge and/or evacuation from the building. A detailed log with staff signatures of training received shall be maintained. All employees shall be trained annually as required in the following plans and shall be kept informed with respect to their duties under the plans. A copy of the plans and the specific emergency numbers related to that type of disaster shall be readily available at all times. Each of the following plans shall be exercised annually:

(a) Fire Safety Procedures Plan shall include:

1. Minor fires;

2. Major fires;

3. Fighting the fire;

4. Evacuation procedures;

5. Staff functions.

(b) Tornado/Severe Weather Procedures Plan shall include:

RULES
OF
TENNESSEE DEPARTMENT OF HEALTH
DIVISION OF HEALTH CARE FACILITIES

CHAPTER 1200-24-5
REVIEW OF HEALTH CARE FACILITY CONSTRUCTION PLANS AND SPECIFICATIONS

TABLE OF CONTENTS

1200-24-5-.01 DEFINITIONS.

(1) Board. The Board for Licensing Health Care Facilities.

(2) Construction. The erection of a new building, an addition to an existing building, a change of occupancy, an alteration that reconfigures the exit arrangement, fire-resistive assemblies, or type of construction, or involves the installation of fire suppression or detection systems or fuel fired equipment. The term construction shall not be construed to include excavation or site preparation.

(3) Department. The Department of Health.

(4) Division. The Division of Health Care Facilities.

(5) Health care facility. Includes any hospital, recuperation center, nursing home, home for the aged, alcohol and drug prevention and/or treatment facility, birthing center, ambulatory surgical treatment center, or residential HIV supportive living facility required to be licensed in accordance with Tennessee Code Annotated § 68-11-201.

(6) N.F.P.A. The National Fire Protection Association.

(7) Occupancy type. Business occupancy, residential occupancy, health care institution occupancy as defined in the 2000 edition of the Life Safety Code (NFPA 101-2000).

Authority: *T.C.A. §§4-5-202, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed April 10, 2000; effective June 24, 2000. Amendment filed February 18, 2003; effective May 4, 2003.*

1200-24-5-.02 SUBMISSION OF PLANS.

(1) No person, partnership, association, corporation, or any state, county or local government unit, or any division, department, board or agency thereof shall commence construction of any health care facility until plans and specification have been submitted to and approved in writing by the Department.

(2) Any construction may be undertaken prior to approval of final plans and specification if:

(a) The phased plans adequately describing the nature and scope of the project have been submitted to the Department; and

(b) Complete plans and specification for that phase of construction to be undertaken have been submitted to the Department, and such plans and specifications have been approved in writing.

504

(Rule 1200-24-5-.02, continued)

(3) The Department has failed to transmit a written evaluation of such plans and specifications within thirty (30) working days after receipt thereof.

(4) In the event that submitted materials do not appear to satisfactorily comply with the existing codes, the department shall furnish a letter to the party submitting the plans which shall list the particular items in question and request further explanation and/or confirmation of necessary modifications.

(5) Resubmission of the complete plans and specifications for any proposed project which is identical in structure and interior arrangement to one already reviewed and approved in accordance with this chapter is required, however, the Department may reduce the review fee for resubmission.

Authority: *T.C.A. §§4-5-202, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed April 10, 2000; effective June 24, 2000.*

1200-24-5-.03 FEES.

~~(1) The fee schedule for review of plans and specifications for construction shall be as specified in the following table:~~

~~Total Construction Cost:~~	~~Fee:~~
~~$ 1.00 to $ 50,000~~	~~$260.~~
~~$ 50,001. to $ 100,000.~~	~~$260. for the first $50,000., plus $3.00 for each additional thousand or fraction thereof, to and including $100,000.~~
~~$ 100,001. to $ 500,000.~~	~~$410. for the first $100,000., plus $2.00 for each additional thousand or fraction thereof, to and including $500,000.~~
~~$ 500,001. and up~~	~~$1,210. for the first $500,000., plus $1.50 for each additional thousand or fraction thereof, with a maximum of $20,000.~~

(1) The fee schedule for review of plans and specifications for construction shall be specified in the following table:

Total Project Construction Cost	Fee
$0.00 to $1,000,000.00	$2.50 per thousand or fraction thereof ($250.00 minimum)
$1,000,000.01 or more	$2,500.00 for the first $1,000,000.00 plus $2.00 for each additional thousand or fraction thereof.

(2) The fee shall be payable and due at the time of initial submission of plans and specifications.

(a) The fee for obtaining a letter stating that plans are not required to be reviewed (a "no review letter") shall be one hundred dollars ($100.00).

(Rule 1200-24-5-.03, continued)

(b) The fee shall be applied to the fee for review of plans and specifications for construction if it is determined that plans are required to be reviewed.

(3) The fee for review of plans and specifications for minor renovations, locking hardware, hood and duct suppression shall be three hundred dollars ($300.00).

(4) The fee for review of plans and specifications for Homes for the Aged (RHAs) licensed for six (6) beds or fewer shall be three hundred dollars ($300.00).

(~~3~~5) Filing fees are non-refundable and must be received by the Department prior to beginning the required thirty-day review cycle.

(46) If plans and specifications must be resubmitted due to the expiration of the twelve (12) month approval period as specified under Rule 1200-24-5-.04, a new fee established under these rules shall be imposed. Extensions to the approval period may be granted upon submission of written request to the Department.

(~~5~~7) The Department may require appropriate documentation of cost, such as, contractors' bids or invoices if:

(a) In its opinion, the construction cost of a project has been underestimated in the certification submitted pursuant to these rules; or

(b) The scope of a project is substantially revised after initial plans submission.

Authority: *T.C.A. §§4-5-202, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-216, and 68-11-804.* ***Administrative History:*** *Original rule filed April 10, 2000; effective June 24, 2000. Amendment filed February 28, 2002; effective May 14, 2002.*

1200-24-5-.04 APPROVAL OF PLANS.

(1) Plans and specifications submitted pursuant to these rules shall be approved only if the proposed construction would be in compliance with the minimum standards of fire prevention, fire protection, and building construction safety in effect at the time of initial submission.

(2) No final approval of plans and specifications shall be valid unless the construction represented by such plans and specifications has substantially progressed within twelve (12) months after the effective date of any adopted revisions of the building or codes standards in effect at the time of initial submission.

(3) A copy of the approved plans and specifications shall be retained on the job site through completion of the project and final inspection.

(4) Construction shall proceed in accordance with the plans and specifications as approved hereunder. If construction is completed in accordance with the approved plans and specifications, the building represented by such plans and specifications shall be exempt from subsequently adopted standards of fire prevention, fire protection, and building construction safety, unless the non-conformity of the building to such standards poses a serious life safety hazard.

(5) No approval of, or failure to review, plans and specifications by the Department shall relieve the owner, developer, designing architect or engineer of their respective responsibilities for compliance

(Rule 1200-24-5-.03, continued)

with applicable laws, rules or codes respecting fire prevention, fire protection, and building construction safety.

Authority: *T.C.A. §§ 4-5-202, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed April 10, 2000; effective June 24, 2000.*

1200-24-5-.05 INSPECTION OF CONSTRUCTION.

(1) When the Department inspects any construction pursuant to these rules, the inspector shall determine only whether the construction conforms to the approved plans and specification; except, however, that if such plans and specifications are not specific with respect to any applicable standard, the inspection shall be made to that standard.

(2) If upon final inspection or re-inspection of the completed project, the Department's inspector finds that only minor items remain to be completed or corrected which do not significantly affect the health or safety of the occupants, the inspector shall recommend to the Department permission to occupy, pending completion or correction of such items.

Authority: *T.C.A. §§4-5-202, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed April 10, 2000; effective June 24, 2000.*

If a roll-call vote was necessary, the vote by the Agency on these rulemaking hearing rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)
Dr. Larry Arnold	X				
Sylvia J. Burton	X				
Dr. Thomas M. Carr, Jr.				X	
Paula L. Collier	X				
Betsy Cummins	X				
Alex Gaddy	X				
Robert Gordon, Ph.D.	X				
Dr. Jennifer Gordon-Maloney				X	
C. Luke Gregory				X	
Mike Hann				X	
Janice M. Hill, R.N.	X				
Dr. Roy King				X	
Carissa S. Lynch, Pharm.D.	X				
Annette Marlar	X				
John Marshall	X				
Sara Snodgrass	X				
James V. Weatherington				X	

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Board for Licensing Health Care Facilities on 11/10/2010, and is in compliance with the provisions of TCA 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: *09/17/10*

Rulemaking Hearing(s) Conducted on: (add more dates). *11/10/10*

Date: 7/21/11.

Signature: Alison G. Cleaves

Name of Officer: Alison G. Cleaves

Title of Officer: Chief Deputy General Counsel, Department of Health

Subscribed and sworn to before me on: 7/21/11

Notary Public Signature: T. Theodora P. Wilkins

My commission expires on: 7/7/2011

THEODORA P. WILKINS NOTARY PUBLIC AT LARGE DAVIDSON COUNTY, TENN.

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Robert E. Cooper, Jr.
Attorney General and Reporter
8-1-11

Date

Department of State Use Only

Filed with the Department of State on: 01/03/2012

Effective on: 04/02/2012

Tre Hargett
Secretary of State